UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

United States of America, and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin and the District of Columbia, and the Cities of Chicago and New York, Plaintiffs, *ex rel.* Michael Johnson and Frank J. Strobl, M.D., Ph.D., Relators, v. THERAKOS, INC., ORTHO-CLINICAL DIAGNOSTICS, INC. JOHNSON & JOHNSON, THE GORES GROUP, and MALLINCKRODT plc. Defendants.	Civil Action No. 12-cv-1454 **FILED UNDER SEAL** **Pursuant to 31 U.S.C. §3730(b)(2)** **JURY TRIAL DEMANDED**

THIRD AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

I. INTRODUCTION

1. This is an action, brought by Relators Michael Johnson ("Mr. Johnson") and Frank J. Strobl, M.D., Ph.D. ("Dr. Strobl") (collectively, "Relators"), to recover damages and civil

penalties on behalf of the United States of America, and state and local governments arising out of false claims and records presented by Defendants Therakos, Inc., Ortho-Clinical Diagnostics, Inc., Johnson & Johnson, The Gores Group and Mallinckrodt plc (collectively, "Defendants") to the United States and to the States, the District of Columbia, and the Cities of Chicago and New York (the "*Qui Tam* States").

2. This action arises under the provisions of Title 31 U.S.C. §3729 *et seq*., popularly known as the False Claims Act (the "FCA"), and pursuant to analogous provisions of state and local law, including, but not limited to the following:

California False Claims Act, Cal. Gov't Code § 12651 *et seq*.
Colorado Medicaid False Claims Act, Rev. Stat. § 25.5-4-304 *et seq*.
Connecticut False Claims Act, Chapter 319v § 17b-301a *et seq*.
Delaware False Claims and Reporting Act, Del. Code Tit. 6, § 1201 *et seq*.
Florida False Claims Act, Fla. Stat. § 68-081 *et seq*.
Georgia False Medicaid Claims Act, Ga. Code § 49-4-168 (2007)
Hawaii False Claims Act - False Claims to the State, Haw. Rev. Stat. § 661-21 *et seq*.
Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175/1 *et seq*.
Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq*.
Iowa False Claims Act, Iowa Code Ann. § 685.1 *et seq*.
Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437.1 *et seq*.
Maryland False Claims Act, Md. Code Ann., Health-Gen. § 2-6-1 *et seq*.
Massachusetts False Claims Act, Mass Laws Ch. 12, § 5(A) *et seq*.
Michigan Medicaid False Claims Act, Mich. Comp Laws Serv. § 400.601 *et seq*.
Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*.
Montana False Claims Act, Mont. Code § 17-8-401 *et seq*.
Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. § 357.010 *et seq*.
New Hampshire Medicaid False Claims Act, N.H. Rev. Stat. § 167:61-b *et seq*.
New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq*.
New Mexico Medicaid False Claims Act., N.M. Stat § 27-14-1 *et seq*.
New York False Claims Act, N.Y. St. Fin. Law § 187 *et seq*.
North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*.
Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq*.
Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*.
Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq*.
Tennessee Medicaid False Claims Act, Tenn. Code § 71-5-181 *et seq*.
Texas Medicaid Fraud Prevention, Tex. Hum. Res. Code § 36.001 *et seq*.
Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq*.
Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. § 48.80.010 *et seq*.

Wisconsin False Claims Act, Wis. Stat. § 20.931 *et seq.*
District of Columbia False Claims Act, D.C. Code § 2-308.13 *et seq.*
City of Chicago False Claims Act, Mun. Code, § 1-22-010 *et seq.*
New York City False Claims Act, Adm. Code § 7-801 *et seq.*

(collectively, "State *Qui Tam* statutes").

3. This case is brought pursuant to the *qui tam* provisions of the federal FCA, 31 U.S.C. § 3729 *et seq.*, and pursuant to analogous provisions of state and local law, to recover treble damages and civil penalties on behalf of the United States of America and the *Qui Tam* States, arising from false or fraudulent claims for reimbursements for prescription drugs that were submitted or caused to be submitted by Defendants to federal government-funded programs including, without limitation, Medicaid, Medicare, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, and the Veterans Administration in violation of the FCA. The FCA specifically proscribes Defendants' conduct involving unlawful marketing of prescription drugs, illegal kickbacks, and thus the submission of false or non-reimbursable claims to Medicaid and other government-funded health programs.

4. Defendant Therakos has developed and sells certain combined drug and medical device systems that perform a procedure called photopheresis (the "Product"). The Product operates through a process of separating, collecting and treating blood cells with the drug component of the Product, before these blood cells are subsequently re-infused into the patient's body.

5. Relator Johnson is a current Therakos sales representative. He has been working for Defendant Therakos since 2001.

6. Relator Johnson markets and promotes the Therakos photopheresis device system, which is solely indicated for the treatment of cutaneous T-cell lymphoma ("CTCL"), a type of non-Hodgkin lymphoma. According to the Lymphoma Research Foundation, CTCL accounts for only

2 to 3% of all cases of non-Hodgkin lymphoma and mostly affects adults. In the United States, there are only about 1,500 new cases of CTCL per year. Only a very small fraction (less than 5%) of those CTCL patients will ever benefit from ECP therapy. There are approximately 20,000 to 30,000 CTCL patients and less than 5% of those patients will develop Sézary Syndrome; ECP is the primary treatment for this variant.

7. Relator Dr. Strobl was the Director of Scientific Affairs for Therakos from 2002 to 2007.

8. Relator Dr. Strobl witnessed, first-hand, the off-label and improper promotion of the Therakos photopheresis device system.

9. Defendants' off-label and other illegal marketing activities in violation of the FCA and United States Food and Drug Administration ("FDA") laws and regulations included, but were not limited to:

a. instructing Therakos sales representatives, including Relator, to market and promote the Product to organizations and physicians who would use it for something other than its FDA-approved use;

b. instructing Therakos sales representatives, including Relator, to prepare annual Sales Plans that included the successful closing of specific off- label organizations;

c. instructing Therakos sales representatives, including Relator, to illegally market the Product was for use in pediatric cases of pediatric bone marrow transplant and CTCL; and

d. increasing sales quotas for Therakos sales representatives even though Therakos knew that the medical condition for which the Product was FDA-approved (CTCL) was extremely limited.

10. Defendants' FCA violations and their various marketing schemes corrupted the independent medical judgment of physicians, unlawfully increased costs to the United States and the *Qui Tam* States, and risked patients' health by improperly influencing physicians' decisions about whether to prescribe the Therakos photopheresis device system.

11. Defendants knew or should have known that their unlawful activities would cause physicians and other healthcare professionals to routinely file false claims for reimbursement from the Federal and State governments in violation of the FCA and state and local law, and involved violations of the Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et seq*., the Food and Drug Administration and Modernization Act of 1997, 21 U.S.C. § 351 *et seq*. and 21 U.S.C. § 360aaa *et seq*., the Medicare/Medicaid Fraud & Abuse Anti-Kickback Statute, 42 U.S.C. § 1320a *et seq*., the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8, and similar state laws.

12. Because of Defendants' unlawful promotion scheme, patients receiving Defendants' Product for unapproved and unproven uses, and received no assurance that their doctors were exercising their independent and fully-informed medical judgment.

13. Defendants' schemes illegally increased the federally-funded and state-funded market share for the Product. The federal and state governments consequently paid enormous sums for reimbursement claims they would have rejected had each been aware of Defendants' illegal actions. Moreover, as a result of Defendants' illegal promotions, the public over-utilized Defendants' Product and costs to the federal and state governments soared, while Defendants increased their profits substantially.

14. Defendants chose to promote off-label uses of its Product, despite Defendants' awareness of the FDA's prohibition of off-label marketing.

II. JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction to this Court over actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. This Court also has subject matter jurisdiction over the counts relating to the State False Claims Acts pursuant to 31 U.S.C. § 3732(b),

as well as supplemental jurisdiction over the counts relating to the State False Claims Acts pursuant to 28 U.S.C. § 1367.

16. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in this state and this judicial district. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one act proscribed by 31 U.S.C. § 3729 occurred in this district.

17. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)-(c). Defendants transact business within this District and because acts proscribed by 31 U.S.C. § 3729 occurred in this District.

18. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint is filed under seal and will remain under seal for a period of 60 days or more from its filing date or such other date as the Court so orders, and shall not be served upon the Defendants unless the Court so orders.

19. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any other location as the term "publicly disclosed" is defined in 31 U.S.C. § 3730 (e)(4)(A), amended by Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010). Relators have, however, affirmatively disclosed the allegations herein to the United States Department of Justice, including prior to filing this case.

20. To the extent that there has been a public disclosure of the information upon which the allegations of this Second Amended Complaint are based that is unknown to Relators, Relators are an original sources of this information as defined in 31 U.S.C. § 3730(e)(4)(B), amended by Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902

(2010) and similar state law provisions. Relators possess direct and independent knowledge of the information as a result of an independent investigation they personally conducted into Defendants' wrongdoing, which they acquired in the course of their employment with Defendants and thereafter, as a result of their investigation. Relators voluntarily provided the government with this information prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

21. Relators have independent and personal knowledge of all matters herein.

22. Relator Johnson voluntarily presented this information to the federal government on several occasions prior to filing this lawsuit.

III. THE PARTIES

23. Relator Michael Johnson, an individual citizen residing in the Commonwealth of Pennsylvania, was hired by Therakos in July 2001 as a Sales Representative. Relator is now a Senior Account Manager. He has sold Therakos photopheresis systems since he began with Therakos.

24. Relator Frank J. Strobl, M.D., Ph.D., an individual citizen residing in the Commonwealth of Pennsylvania, served as Therakos' Director of Scientific Affairs from 2002 to 2007. Dr. Strobl also served on Therakos' Management Team in 2006 and 2007.

25. As the Director of Scientific Affairs, Dr. Strobl established and managed Medical Science Liaison and Field Technical Support teams and provided scientific and medical support for the global sales force.

26. When Dr. Strobl was hired in 2002, he reported to William Skillman, Therakos' Vice-President for Worldwide Sales and Marketing. In 2004, Dr. Strobl began to report to Dennis DeCola, Vice President of Compliance and Scientific Affairs. Then, in 2006, Dr. Strobl reported directly to the General Manager at the time, Ingrid Clark Durfy.

27. Defendants Therakos, Inc. (f/k/a Therapeutic Systems, Inc.) is a corporation organized, existing, and doing business under the laws of the State of Florida. Therakos' office and principal place of business are now located in Raritan, New Jersey. Therakos also has offices in Exton, Pennsylvania. Therakos develops and sells certain combined drug and medical device systems, that at all relevant times were approved by the U.S. Food & Drug Administration ("FDA") solely to treat a specialized disease known as "T-cell lymphoma", falling under the jurisdiction and regulation of FDA, throughout the United States.

28. At all times, Therakos acted by and through its agents, servants, workers, employees, officers and directors, all of whom were acting through the course and scope of their actual and apparent authority, agency, duties or employment.

29. Defendant Ortho-Clinical Diagnostics, Inc. ("OCD") is a corporation organized, existing, and doing business under the laws of the State of New York. OCD's office and principal place of business is located in Rochester, New York. At all times, OCD acted by and through its agents, servants, workers, employees, officers and directors, all of whom were acting through the course and scope of their actual and apparent authority, agency, duties or employment.

30. Defendant Johnson & Johnson ("J&J") is one of the world's largest manufacturers of healthcare products for consumer and pharmaceutical markets. J&J is incorporated in New Jersey and headquartered at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J, through its operating companies, designs, manufactures, produces, formulates, labels, advertises, sells, markets, promotes, distributes either directly or indirectly through third parties or related entities numerous pharmaceuticals and healthcare products, in Pennsylvania and nationwide. At all times, J&J acted by and through its agents, servants, workers, employees, officers and directors, all

of whom were acting through the course and scope of their actual and apparent authority, agency, duties or employment.

31. J&J formerly referred to Therakos, as well as other J&J-owned and/or -controlled companies comprising its pharmaceutical empire, as part of the "Johnson & Johnson Family of Companies." Similarly, on its website, Therakos formerly touted itself as "a division of Ortho Clinical Diagnostics, part of the Johnson & Johnson Family of Companies."

32. In or around January 2013, Defendant The Gores Group acquired Therakos from OCD.

33. Defendant The Gores Group is a global investment firm headquartered in Los Angeles, California. At all times, The Gores Group acted by and through its agents, servants, workers, employees, officers and directors, all of whom were acting through the course and scope of their actual and apparent authority, agency, duties or employment.

34. After acquiring Therakos, The Gores Group hired Michael Rechtiene, a former Therakos employee, as Therakos' new CEO.

35. Much of the same conduct described below that occurred when Therakos was owned by the J&J Defendants continued during The Gores Group's ownership.

36. Defendant Mallinckrodt Inc. ("Mallinckrodt") is a pharmaceutical manufacturer incorporated under the laws of Delaware, with its U.S. headquarters at 675 McDonnell Blvd., Hazelwood, Missouri.

37. Mallinckrodt purchased Therakos from The Gores Group in September 2015 for approximately $1.33 billion.

38. Mallinckrodt is a global specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents.

39. Much of the same conduct complained of below that occurred when Therakos was owned by both the J&J Defendants and The Gores Group continues to today under Mallinckrodt's ownership. In other words, the conduct that occurred when Therakos was owned by OCD and The Gores Group continues after Mallinckrodt purchased Therakos.

40. Relators served on the federal and state governments a detailed and comprehensive "written disclosure of substantially all material evidence and information the person possesses", as required by 31 U.S.C. § 3729(b)(2) (the "Disclosure Statement"). Moreover, since that time, Relators have provided numerous supplemental written disclosures, as well as other evidence. These numerous productions have included hundreds of internal emails, training documents, sales materials, sales representative call plans, and other documentary evidence that corroborate the facts alleged in the original Complaint, as well as this Third Amended Complaint.

41. Relators' evidentiary materials also establish Defendants' knowledge of, endorsement of and participation in a nationwide scheme to target providers that submitted for reimbursement by government-funded healthcare programs.

42. Accordingly, by and through the conduct complained of herein, Defendants have caused numerous reimbursement claims from healthcare providers to be submitted to government-funded healthcare programs, including Medicaid, Medicare, CHAMPUS/Tricare or the VA

IV. REGULATORY FRAMEWORK

A. Federal and State Government Health Programs

43. The federal and state governments, through their Medicaid and Medicare programs, are among the principal purchasers of Defendants' products.

44. Medicare is a federal government health program primarily benefitting the elderly created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"). Medicare began paying for over-the-counter drugs or for most self-administered prescription drugs after the Medicare Prescription Drug Improvement and Modernization Act of 2003 was fully implemented.

45. Congress created Medicaid at the same time it created Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program that provides payment of medical expenses to low-income patients. Funding for Medicaid is shared between the Federal government and those State governments participating in the program. The Federal government also separately matches certain State expenses incurred in administering the Medicaid program. While specific State Medicaid coverage guidelines vary, Medicaid's coverage and reimbursement requirements are generally modeled after Medicare's coverage.

46. Medicaid is a joint federal-state program that provides healthcare benefits for certain groups, primarily the poor and disabled. The federal involvement in Medicaid is largely limited to providing matching funds and ensuring that states comply with minimum standards in the administration of the program.

47. Until the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicaid coverage for prescription drugs was significantly more expansive than that provided by Medicare. Nearly every state includes prescription drug coverage in its Medicaid plan.

48. TRICARE is the healthcare system of the United States military, designed to maintain the health of active duty service personnel, provide healthcare during military operations, and offer healthcare to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The program operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian healthcare providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian healthcare providers. Military prescription drug benefits are provided through three programs: military treatment facility outpatient pharmacies, TRICARE contractor retail pharmacies, and a national contractor's mail-order service.

49. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for about 8 million federal employees, retirees, and their dependents. FEHBP is a collection of individual healthcare plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan.

50. FEHBP plans are managed by the Office of Personnel Management.

B. The False Claims Act

51. Originally enacted in 1863, the False Claims Act was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States. The Act was again

strengthened by additional amendments in 2009 and 2010. The 2009 amendments expanded Defendants liability, strengthened retaliation protections, and made it easier for federal, state, and local governments to prosecute FCA actions. The 2010 amendments clarified the definition of who is an "original source" of a FCA disclosure.

52. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to $21,562.80 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1), (2), (7). The FCA empowers private persons who have information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any Defendants. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

53. Knowingly paying kickbacks or undisclosed price discounts to physicians to induce them to prescribe a reimbursable drug, and promoting off-label uses of such drugs by a person who seeks reimbursement from a Federal Government health program for the drug, or who causes an other to do so, while certifying compliance (o r while causing another t o so certify) with the Medicare Fraud & Abuse/Anti-Kickback Statute, the Medicaid Rebate Statute, and the Food, Drug and Cosmetics Act, or billing the Government as if in compliance with these laws, violates the FCA.

C. FDA Regulation of Drug Marketing and Advertising

54. The FDA regulates drugs based on the "intended uses" for such products. A manufacturer that wishes to market any new drug must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a), 360b(a).

55. The Food and Drug Act requires that all "new drugs," 21 U.S.C. § 321(p), be approved by the FDA as safe and effective prior to marketing. The marketing of a new drug without pre-approval from the FDA violates 21 U.S.C. §§ 355 and 331(d), of the Food, Drug and Cosmetics Act.

56. The FDA reviews a pharmaceutical manufacturer's application for approval of a new drug to determine whether the drug's intended use is safe and effective. 21 U.S.C. § 355. "Off-label" refers to the marketing of an FDA-approved drug for uses that have not undergone FDA scrutiny and approval, i.e., for purposes not approved by the FDA.

57. Each State Medicaid program has the power to exclude any drug from coverage if the prescription is not issued for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B). A "medically accepted indication" includes only those indications approved by the FDA and certain "off-label" uses that are "supported by one or more citations included, or approved for inclusion, in any of the compendia" listed in the statute. 42 U.S.C. § 1396r-8(k)(6). Many States further restrict drugs by use of formularies or prior approval processes that aim to restrict off-label uses.

58. Once a drug is approved for a particular use, the FDA allows doctors to prescribe the drug for medical uses that are different from those approved by the FDA. The FDA also allows doctors to request information from drug manufacturers about off-label uses of FDA-approved

drugs. However, with very few exceptions, the FDA prohibits drug manufacturers from marketing, advertising, or promoting a drug for a use that the FDA has not approved.

59. Pursuant to the Food, Drug and Cosmetics Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates, among other things, the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies in promoting and selling FDA-approved prescription drugs. In particular, sales representatives who engage in personal interactions with providers may not promote drugs for use outside the FDA approved label and indications.

60. Any failure by a pharmaceutical company to fairly and accurately represent the approved uses, safety and other required information about a prescription drug is considered misbranding and is, as a matter of law, a false and fraudulent statement. 21 U.S.C. §§ 331(a)-(b), 352(a),(f),(n).

61. Any presentations, promotions, or marketing to physicians of products for use in a manner other than that approved for labeling purposes by the FDA is considered off-label marketing and is proscribed by the FDA. 21 U.S.C. §§ 331(a)-(b), 352(a),(f).

62. FDA regulations, summarized in Defendants' corporate compliance codes, prohibit pharmaceutical companies from actively discussing or detailing off-label uses of drugs in a promotional manner and/or misrepresenting product efficacy and safety. If a physician makes an unsolicited request for information about an off-label use of a drug, a sales representative may not respond except to request information from Defendants' Medical and Drug Information Desk and/or delivering to the physician's office any articles or studies that address the physician's inquiry and are approved by Defendants' pharmaceutical Product Review Committee and filed with

the FDA. FDA regulations, however, prohibit representatives from discussing or detailing studies of off-label uses under any circumstance.

63. Verbal use of Defendants Medical Drug Information is a prohibited practice because the Food, Drug, & Cosmetics Act, 21 U.S.C. § 360aaa *et seq*., requires that the off-label promotion only be disseminated to doctors in writing, that the written materials meet applicable scientific criteria, and that the materials be properly disclosed in advance to the FDA.

64. False marketing and advertising claims of pharmaceutical efficacy and false claims of comparative superiority are prohibited under the Food, Drug & Cosmetics Act. 21 C.F.R. § 202.1(e)(6)(ii).

65. The FDA prohibits manufacturers from making claims in drug marketing materials that the FDA previously rejected and were not included in the package insert. Thus, a marketing scheme utilizing such claims is prohibited by FDA marketing and advertising statutes and regulations. 21 C.F.R. § 202.1.

66. The United States and the States would not have issued reimbursements for off-label sales had they known the truth about Defendants' illegal marketing scheme. Every reimbursement sought from Medicaid, Medicare, and other government healthcare programs for such purchases or prescriptions as a result of Defendants' aggressive and illegal off-label marketing constitutes a false claim under the FCA.

D. The Medicare Fraud & Abuse/Anti-Kickback Statute

67. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also covers Medicaid, provides penalties for individuals or entities that knowingly and will fully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health

benefits program. The offense is a felony punishable by a fine of up to $25,000 and imprisonment for up to 5 years.

68. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals, or from receiving remuneration that takes into account the volume or value of any referrals or business generated. 42 C.F.R. § 1001.952(f). Remuneration paid to providers is an illegal kickback when it is paid to induce or reward the drug prescriptions written by physicians. Kickbacks are harmful to public policy because they increase the expenditures paid by government-funded health benefit programs by inducing medically unnecessary use of prescription drugs and excessive reimbursements. Such kickbacks also reduce a patient's healthcare choices as unscrupulous or unknowing physicians steer their patients to various drug products based on the physician's own financial interests rather than the patient's medical needs.

69. The Medicare Anti-Kickback Statute provides eight statutory exceptions from its statutory prohibitions, and certain regulatory "safe harbors" have been promulgated to exclude certain types of conduct from the reach of the statute. 42 U.S.C. § 1320a-7(b)(3). None of the available statutory exceptions or regulatory safe harbors protect the Defendants' conduct in this case.

70. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of any individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party violated the Medicare Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended the Act to include administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three

times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. 42 U.S.C. § 1320a-7a(a)(7).

71. As detailed below, Defendants' pharmaceutical marketing repeatedly violated provisions of the Anti-Kickback Statute and the FCA because Defendants' improper kickbacks and incentives induced physicians to prescribe Defendants' drugs when they otherwise would not have and many of those prescriptions were paid for by Medicaid and other Government funded health insurance programs.

72. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a per se prohibition against kickbacks.

73. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under Medicare, Medicaid, and/or TRICARE/CHAMPUS programs.

E. Stark Law - The Medicare/Medicaid Self-Referral Statute

74. The Medicare/Medicaid Self-Referral Statute, 42 U.S.C. § 1395nn *et seq*., known as the "Stark" law, prohibits a pharmaceutical manufacturer from paying remuneration to physicians for referring Medicaid patients to the manufacturer for certain "designated health services," including drug prescriptions, where the referring physician has a nonexempt "financial relationship" with that manufacturer. 42 U.S.C. § 1395nn(a)(1), (h)(6). The Stark law provides that

the manufacturer shall not cause to be presented a Medicaid claim for such prescriptions. The Stark law also prohibits payment of Medicaid claims for prescriptions rendered in violation of its provisions. 42 U.S.C. § 1395nn(a)(1), (g)(1).

75. Defendants' marketing of its drugs repeatedly violated the provisions of the Stark law and the FCA because Defendants' unlawful payments, services, and excessive samples provided to prescribing physicians induced those physicians to prescribe these and other drugs when they otherwise would not have, and many of those prescriptions were paid for by Medicaid and other Government funded health insurance programs.

V. THERAKOS' PRODUCT

76. Cutaneous T-cell lymphoma ("CTCL") is a type of non-Hodgkin lymphoma, a condition in which lymphocytes, a type of white blood cell, become cancerous and affect the skin. Patients may experience symptoms of thickened, red, cracking, scaling or intensely itchy skin in localized areas or all over the body. Some patients experience blood, lymph node and/or internal organ involvement with serious complications.

77. According to the Lymphoma Research Foundation, CTCL accounts for about 2-3% of all cases of non-Hodgkin lymphoma and mostly affects adults. In the United States, there are approximately 1,500 new cases of CTCL per year.

78. Defendant Therakos develops and sells certain combined drug and medical device systems that perform a procedure called photopheresis. These systems operate through a process of separating, collecting and treating blood cells with the drug component of the instrument, before these blood cells were subsequently re-infused into the patient's body. This process is referred to as extracorporeal (outside the body) photopheresis ("ECP"). *See* Exhibit A (schematic of the ECP process).

79. ECP is performed by using either of Therakos' combined drug/medical device systems -- the UVAR XTS® Photopheresis System or the CELLEX® Photopheresis System. The various Therakos Photopheresis Systems are sold by Therakos to hospitals, medical institutions and physicians.

80. The system (collectively, the "Product") involves a drug, UVADEX® (methoxsalen) Sterile Solution; a kit called a Photopheresis Kit; and a medical device, the UVAR XTS or the CELLEX. *See* Exhibit B (photograph of the UVAR XTS device).

81. Specifically, photopheresis or ECP is a therapeutic procedure performed outside the body using a Therakos Photopheresis system to withdraw a volume of whole blood that is then centrifuged to separate the white blood cells from the red blood cells and plasma. The red blood cells and plasma are immediately returned to the patient. The white blood cells are treated with UVADEX, which is photoactivated after exposure to UVA light. The treated white blood cells are then reinfused into the patient.

82. ECP can be performed either on an inpatient or outpatient basis usually within a hospital setting. The entire procedure is completed within approximately four hours.

83. The Product is *approved solely* to treat CTCL. Indeed, the Prescribing Information for the Product states:

> UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the UVAR™ XTS™ or THERAKOS™ CELLEX™ Photopheresis System in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

See Exhibit C (prescribing information).

84. This FDA-approved indication was necessarily limited to a finite and very narrow group of patients suffering from CTCL, a very specific medical condition, as described above.

85. The FDA recently approved the Therakos CELLEX Photopheresis System for the palliative (reducing the severity of symptoms) treatment of the skin manifestations (appearance) of CTCL that are unresponsive to other forms of treatment.

86. Upon information and belief, Therakos currently markets the only approved integrated systems for ECP in the United States.

87. Even though CTCL is a rare disease, upon information and belief, sales of the Therakos Photopheresis Systems in the United States were $26 million in 2006, $35 million in 2007, and $66 million in 2010. Upon information and belief, Relators allege that sales were more than $70 million in 2011 and approximately $80 million in 2012. As of September 30, 2016, sales were more than $116 million.

88. Upon information and belief, Relators believes that more than 70% of all Therakos sales are off-label uses.

89. In April 1998, CMS issued a national coverage determination for extracorporeal photopheresis providing coverage by Medicare only when used in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that has not responded to other therapy.

90. On December 19, 2006, CMS determined that ECP was reasonable and necessary for:

- Patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment; and
- **Patients with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment.**

91. Accordingly, although FDA has not approved the use of either Therakos system for use with any patient other than for treating CTCL, CMS will reimburse providers who provide care using the Therakos systems.

VI. THE J&J DEFENDANTS AND THERAKOS CONSPIRED TO IMPROPERLY OBTAIN CMS APPROVAL FOR REIMBURSEMENT OF THE PRODUCT

A. Therakos' Financial Concerns, And CMS Approves ECP for Reimbursement

92. In 2005, it was critical for Therakos to obtain permission from CMS for reimbursement from Medicare and Medicaid for ECP treatment for graft-versus-host disease ("GvHD").[1] Therakos needed to sustain and drive future sales growth in the U.S. as the company's clinical trial program (described below) had experienced significant delays and Therakos-sponsored clinical trial results had indicated questionable efficacy for ECP in GvHD and other indications. These setbacks made it clear that eventual *FDA approval* of ECP for GvHD was in doubt and still a number of years away.

93. Accordingly, Therakos requested that certain physicians and medical administrators from across the country support Therakos' attempts to obtain reimbursement approval from CMS for ECP.

94. For example, in or around 2005, Keith Berman, a third-party "reimbursement expert" hired by Therakos to assist in the approval process, asked Relator Johnson to speak to various Therakos customers in his region and ask them to publicly support Therakos' planned efforts to gain approval for the Product. Mr. Berman, acting on behalf of Therakos, instructed Relator Johnson to "lean" on a number of physicians, including:

- Emilio Bisaccia, MD (deceased) - Attending Physician and Medical Director of the Photopheresis Unit, Morristown Memorial Hospital.
- Michelle L. Donato, MD - Chief of the Adult Blood and Marrow Stem Cell Transplantation Program at John Theurer Cancer Center, Hackensack University Medical Center.

[1] In April 1998, CMS had issued a national coverage determination ("NCD") for ECP providing coverage only when used in the palliative treatment of the skin manifestations of CTCL that has not responded to other therapy. In 2005, that remained the only approval for Therakos' Product.

- Francine M. Foss, MD - Professor of Medicine (Hematology) and of Dermatology, Yale School of Medicine.
- Alain H. Rook, MD - Director, Photopheresis Program and Professor of Dermatology, Hospital of the University of Pennsylvania.
- Scott D. Rowley, MD – Chief, John Theurer Cancer Center's Blood and Marrow Stem Cell Transplantation Division, Hackensack University Medical Center.
- Eric C. Vonderheid, MD - Professor of Dermatology and Oncology and Director of Photopheresis program, Johns Hopkins University.

95. In addition, VP of Compliance and Scientific Affairs DeCola asked Relator Dr. Strobl to ask other providers across the United States to publicly support Therakos' planned efforts to gain approval for the Product, including:

- Sunil Abhyankar, MD - Professor of Medicine and Pediatrics and Director, BMT Pheresis & Cell Processing, University of Kansas Hospital.
- Dan R. Couriel, MD - Department of Blood and Marrow Transplantation, M.D. Anderson Cancer Center (now Professor of Internal Medicine, Huntsman Cancer Institute
University of Utah Hospital).
- Michelle L. Donato, MD - Chief of the Adult Blood and Marrow Stem Cell Transplantation Program at John Theurer Cancer Center, Hackensack University Medical Center.
- Francine M. Foss, MD - Professor of Medicine (Hematology) and of Dermatology, Yale School of Medicine.
- Alain H. Rook, MD - Director, Photopheresis Program and Professor of Dermatology, Hospital of the University of Pennsylvania.
- Ravindra Sarode, MD – Professor, Department of Pathology and Medical Director and Chief of Service for Clinical Laboratory Services, University of Texas Southwestern Medical Center.

96. On March 21, 2006, CMS received a letter from the University of Pennsylvania Health System ("UPenn") requesting that CMS update its national coverage determination ("NCD") for ECP by increasing the number of indications for ECP to treat the following four disorders:

- refractory acute cardiac transplant rejection,
- refractory chronic graft versus host disease,
- pemphigus vulgaris, and
- bullous pemphigoid refractory to conventional immunosuppressive therapy.

97. Upon information and belief, Mr. Berman and VP of Compliance DeCola helped draft UPenn's submission and asked UPenn to submit it. Dr. Rook, identified above, was one of the physicians who signed UPenn's request.

98. On April 6, 2006, CMS opened a NCD request to review the coverage of ECP. CMS requested public comment on whether there was adequate evidence, including clinical trials, for evaluating health outcomes of ECP for the requested reimbursement in the Medicare population.

99. That same day, Therakos submitted its own "Request for Medicare National Coverage Determination: Extracorporeal Photopheresis for the Treatment of Refractory Chronic Graft-Versus-Host Disease" (the "ECP CMS Submission") to CMS.

100. Consultant Keith Berman wrote the ECP CMS Submission for Therakos, with the assistance of Relator Dr. Strobl and VP of Compliance DeCola,.

101. Therakos' ECP CMS Submission stated, among other things::

> Under the National Coverage Determination process, Therakos requests that CMS expand its coverage of Extracorporeal photopheresis (ECP) to include extensive chronic graft-versus-host disease (cGvHD) that has failed to respond to corticosteroids and standard immunosuppressive drug therapy.

https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id180comm.pdf.

102. Relator Johnson specifically requested that certain physicians provide comments on UPenn's and Therakos' submissions, including Ellen Kim, M.D. (a Professor of Dermatology at UPenn), Dr. Emilio Bisaccia (Morristown Memorial Hospital, NJ), Joseph Antin, M.D. (Chief, Adult Oncology Hematopoietic Stem Cell Transplantation Program, Dana-Farber Cancer Institute,

Boston), Francisco J. Bolanos-Meade, M.D. (Associate Professor of Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD), Steve M. Horwitz, M.D. (Oncologist, Memorial Sloan Kettering, NY, NY) and Larisa Geskin, M.D. (Associate Professor of Dermatology at Columbia University Medical Center and Director of the Comprehensive Skin Cancer Center (CSCC) at the Division of Cutaneous Oncology in the Department of Dermatology) when she was a physician at the University of Pittsburgh Medical Center (UPMC).

103. As stated above, less than nine months later, CMS determined that ECP was reasonable and necessary for refractory GvHD.

B. Therakos Conducts Three Clinical Trials, Fails to Present Damning Information to CMS and Misuses the Trial Results in Sales Calls

104. In or around 2002, Therakos had begun to prepare three different Phase II ECP/GvHD trials. Phase II trials are "feasibility" studies that provide companies with important information on study design, safety, efficacy, and, perhaps most importantly, the likelihood of success of the subsequent, larger, more expensive *Phase III* trials necessary for FDA approval.

105. Relator Dr. Strobl was not an official member of the clinical trial team, but he assisted in recruiting sites (both in the U.S. and globally) for the trials and helped manage relationships with the study investigators.

106. Relator Dr. Strobl also helped the Therakos sales and marketing department develop and clarify "promotional" messaging for customers based on the results of Therakos' Phase II trials.

107. Although Therakos never generated official sales/promotional material to communicate the results of these trials, Therakos scientific, marketing, and sales employees used the results proactively in their discussions/sales calls with existing and potential customers to drive

ECP use for GvHD. The results and subsequent messaging were an important part of CME programs and other presentations sponsored by Therakos.

108. The initial three Phase II trials using ECP were meant to show efficacy and safety for the following conditions:

- Prior to allogeneic bone marrow transplant to prevent the development of GvHD after transplant (the "Prevention Study");
- To treat acute GvHD (the "Acute Trial"); and
- To treat chronic GvHD (the "Chronic Trial").

109. Although the results of the Prevention Study showed a possible delay (but not a lower incidence) in the development of acute GvHD and also a possible increased overall survival in ECP-treated patients compared to historical control patients (who were treated similarly but without ECP), Therakos decided the results were not convincing enough to pursue a Phase III clinical trial program for this indication.

110. Nevertheless, Therakos used these results to proactively "message" and engage physicians to begin using ECP to prevent or treat GvHD. For example, Therakos sales representatives were instructed to make statements such as "ECP may prevent the development of acute GVHD when used prior to transplant" and "ECP may also improve your overall survival rates if you use ECP prior to transplant."[2]

111. The Acute Trial failed from the start because Therakos was unable to enroll patients, and many of the investigators thought the study design of the Acute Trial was significantly flawed.

[2] The various representations or paraphrases of sales statements included in this Third Amended Complaint, and indicated by quotation marks throughout, were made by Therakos employees who engaged customers, including medical science liaisons, sales representatives, engineers, research scientists, field trainers, and members of Therakos management who had client contact, including

112. However, this failure did not prevent Therakos from proactively discussing the results of studies performed by its customers and relating to the potential benefits of ECP on aGvHD. Relator Dr. Strobl is aware that Therakos used messages that included statements such as "ECP reduces the rate and severity of acute GvHD including the severest forms, Grade III and Grade IV" and "You might be able to reduce the doses of immunosuppressants and thus decrease the side effects your patients are experiencing".

113. In the Chronic Trial, the primary endpoint was a quantitative (%) comparison improvement in skin GvHD after 12 weeks of therapy between patients who received ECP and standard immunosuppressive therapy or standard immunosuppressive therapy alone. The results failed to show a significant difference between the two treatment groups in regards to the primary endpoint.

114. The only positive result of the Chronic Trial for Therakos was that a secondary endpoint analysis suggested ECP might help to reduce the dose of steroids the patients were receiving to treat their chronic GvHD ("cGvHD"). In a follow-up to this study, Therakos utilized the patients who had not received ECP, and treated them for 24 weeks with ECP. After six months of ECP therapy, these patients showed mixed and often non-significant improvement in the cutaneous manifestations and the non-cutaneous (organs such as oral mucosa, liver, lungs, etc.) manifestations of GvHD, and the steroid-sparing effects of ECP.

115. A July 2006 draft of an article discussing the Chronic Trial acknowledges that the Chronic Trial did not achieve the results Therakos was pursuing. The draft stated - "Patients in the ECP treatment arm had a greater median percentage reduction in the TSS at Week 12 (-12.7%) compared to the standard treatment arm (-10.4%) (Table 3). **However, this difference was not**

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the General Managers (M. Rechtiene and I. Clark-Durfy), VP of Compliance (D. DeCola), VP of

statistically significant (p = 0.507)." (emphasis added). The bolded sentence did not make it into the final article.

116. Moreover, as this draft transcript shows, the results of the Chronic Trial were finalized, and even served as the basis for various draft articles, well before CMS had finalized its decision to approve reimbursement in October 2006.

117. Indeed, a comparison of figures used in the draft article, the final published article and other related documents show consistent figures (when not omitted) across the documents, demonstrating that Therakos possessed the figures well before CMS' decision in December 2006, and even before Therakos made its April 2006 submission to CMS. *See infra* ¶¶ ____.

118. At the very least, Therakos should have submitted the Chronic Trial results as an amendment to its ECP CMS Submission.

119. Moreover, Therakos has never initiated a subsequent Phase III trial on the use of ECP in chronic GvHD.

120. Two sales-related documents used by Therakos during this time period demonstrate that the company failed to furnish healthcare providers and citizens with the company's knowledge of the failed Chronic Trial:

a. A sales brochure that was distributed to Relator Johnson and other Therakos sales representatives in 2006 to be used in their promotional and marketing efforts of Therakos' products and services does not include any of the new data from the Chronic Trial.

b. A "Selling Tools" document (dated June 6, 2006) that was used to train Relator Johnson and other Therakos sales representatives did not discuss the

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Sales (Adams), VP of Marketing (S. Snyder), and the VP of Business Development (H. Walder).

new data from the Chronic Trial. The training was conducted by Marcus Girolamo (Manager of Worldwide Marketing at Therakos) and Scott Snyder (Therakos' Vice President of Marketing), and focused on the Product's "proven efficacy" and "superior safety profile." The 11-page training tool failed to inform the Therakos sales representatives of critical information and data related to a crucial Therakos clinical trial. The training aid also showed the Therakos sales representatives how to positon ECP in a physician's treatment regimen.

121. As with many of Therakos' other sales material, the training and related sales aid mentioned *supr*a were based on anecdotal data. Moreover, common messages that Relator Johnson and other Therakos sales representatives took from this training and this sales brochure included:

- "ECP is safe and effective in treating GvHD with little or no side effects"
- "Early intervention with ECP decreases mortality and morbidity"
- "Based on our MOA, ECP has been shown to reduce the inflammatory response by decreasing T-Effector cell function, increasing T-regulatory cells, decreasing pro-inflammatory cytokines and increasing anti-inflammatory cytokines"
- "The use of ECP has been shown to give patients a two-time survival benefit"

122. As with aGvHD, Therakos preemptively discussed the results of studies previously performed by customers on the potential benefits of ECP on cGvHD. Examples of messages used by Therakos included "ECP reduces the rate and severity of chronic GvHD in particular the skin manifestations but also the extra-cutaneous forms of the disease" and "You might be able to reduce the doses of immunosuppressants and thus decrease the side effects your patients are experiencing".

123. Under the direction of Therakos management, the company's sales, scientific affairs, and research employees proactively introduced themselves and engaged in discussions with potential customers, including at professional meetings or at individual office appointments,

regarding the use of ECP to prevent or treat aGvHD or cGvHD, including the use of many of the "messages" described above. Therakos' management board would also regularly request and participate in these introductions/discussions when given the opportunity.

124. Therakos also proactively disseminated promotional messages through Medical Education (CME) symposia (using customer presenters) or through individual presentations given either by customer presenters or, more commonly, by Therakos employees (*i.e.*, Relator Dr. Strobl, Kim Campbell, Ann Bullinger, and Therakos MSLs).

125. Moreover, Therakos sales representatives routinely used, distributed and proactively promoted the use of ECP to treat GvHD by using unapproved reprints on the topic of GvHD, Therakos used these reviews (of scientific papers) as messages explaining how ECP was used to treat GvHD. GM Rechtiene actually authored one of these journal papers.

126. Similarly, Therakos management would distribute copies of the presentations that were given at the Tandem Bone Marrow Transplant meetings in Honolulu, Hawaii to Therakos sales representatives, and it was common for Therakos sales representatives to use those publications for messaging purposes.

127. One "message" that Relator Johnson remembers discussing with physicians was "2 times survival", which meant that by using ECP to treat GvHD the patients would live longer. Relator Johnson believes this specific message arose from an article written by Hildegard Greinix, who was a Professor of Internal Medicine and worked in the Bone Marrow Transplant department at the Medical University of Vienna, Austria.

128. On at least two occasions, in Relator Johnson's territory, Therakos' commercial team held symposiums on the various uses of ECP, including GvHD. Therakos has held similar

events at a number of medical schools and institutions, including at Johns Hopkins University in Baltimore, Maryland.

C. Therakos Withholds the Results of its Chronic Trial from CMS

129. Relator Dr. Strobl coordinated the gathering of the Chronic Trial data in November and December 2005.

130. Upon information and belief, Therakos' reimbursement expert, Keith Berman, drafted Therakos' ECP CMS Submission at the same time.

131. In December 2005, Therakos prepared a "Publication Plan" relating to the results of the Chronic Trial. The presentation shows that Therakos was considering various journals, including *Blood*, *British Journal of Hematology* and *Biology of Blood and Marrow Transplantation*, for the planned article. However, Therakos also stated that its "Current plan is to withhold release of the 'chronic' findings."

132. Further, the December 2005 "Publication Plan" showed that Therakos intended to provide the results to the investigators and a Steering Committee by "Q1/06", or the First Quarter of 2006.

133. Therakos planned to make a "CS [Clinical Study] Report" to the FDA in June 2006 and a "Medicare NCD Application" in August 2006.

134. The "*Original* Rollout Plan" also called for the results of the Chronic Trial to be publicized through numerous CME courses, Advisory Board meetings and the publication of abstracts throughout 2006 and 2007. However, the "*Current* [as of December 2005] Rollout Plan" scrapped many of the plans and pushed other presentations until 2007 or 2008.

135. Therakos also discussed the risks of delaying the "rollout" versus risks of an early "rollout." The latter option (weighing the "worst case scenario" versus the "likely scenario")

included descriptions of reimbursement and the effect of an early rollout on the ECP CMS Submission.

136. Similarly, a document showing "Chronic and Prevention GvHD Data Rollout Plans" from **May** 2006 shows that Therakos knew the results of the Chronic Trial **months before** April 2006. The second slide in the presentation identifies the following dates:

• Last Patient Out	July 2005
• Database Lock	Sept 2005
• Preliminary Data Analysis	Dec 2005
• **Validated Data Analysis**	**Jan 2006**
• Steering Committee Data Review	Feb 2006

137. The "cGvHD" Rollout similarly shows that Therakos possessed relevant data before April 2006 (i.e., "Steering Committee" meeting in April 2006 and a "Clinical Study Report" in July 2006).

138. Thus, Therakos had the results and "validated data" of its chronic GvHD study *several months* before its CMS submission on or about April 6, 2006.

139. The results of the Chronic Trial were clearly relevant to CMS' decision regarding the approval of ECP for reimbursement.

140. However, the results of the Chronic Trial were not provided to CMS in April 2006 with Therakos' ECP submission, even though Therakos possessed the results and underlying data.

141. Further, discussions between Relator Dr. Strobl and Dennis DeCola, Therakos' VP of Compliance and Scientific Affairs, prove that the Chronic Trial failed to meet its primary endpoint and this is why it was not included in the ECP CMS submission.

142. A Therakos presentation from September 2006 also demonstrates that the Chronic Trial failed to meet its endpoints. One slide clearly shows that the "p value" at 12 weeks (.507) is much greater than 0.05; a p value needs to be equal or less than 0.05. This is the first slide in the "Efficacy Data" section of the presentation.

143. Upon information and belief, if the Chronic Trial had met its primary endpoint, Therakos would have included the data in the ECP CMS Submission.

144. Thus, Therakos' CMS submission was incomplete and omitted significant information. Therakos did not inform CMS of the failure to reach the primary outcome of the Chronic Trial even though the data was available because this would have jeopardized CMS approval to reimburse for ECP to treat cGvHD. Indeed, Therakos did not even mention, in its ECP CMS Submission, that it had an ongoing trial for cGvHD.

145. It is highly unlikely that CMS would have approved reimbursement of ECP for treatment of cGvHD if Therakos had provided the data from the Chronic Trial to CMS. Thus, Therakos deliberately delayed "rolling out" the Chronic Trial data until after the CMS submission. Finally, Therakos VP of Compliance and Scientific Affairs Dennis DeCola signed off on this omission.

146. As of October 2016 (more than 9 years following CMS approval of reimbursement), Therakos has failed to obtain FDA approval and has only one active Phase II trial investigating the use of ECP in GvHD.

VII. DEFENDANTS' MARKETING SCHEMES PROHIBITED BY THE FALSE CLAIMS ACT

A. Defendants Marketed and Promoted the Product for Uses Other than those Approved By FDA

147. Relator Johnson has been working in medical sales for more than 22 years.

148. In 2001, Relator Johnson began a job with Therakos, selling the company's only product, a photopheresis system.

149. As stated above, the Product is FDA-approved only for CTCL palliative treatment. The Product includes a corresponding machine for the implementation of the drug and treatment.

150. From the beginning of his employment, Relator Johnson, as well as the other Therakos sales representatives, were instructed to market and promote the Product to organizations and physicians who could use it for something other than the FDA-approved use. The off-label uses were, and continue to be, supported by Defendants in several ways.

1. Therakos Directs Its Sales Representatives to Market the Product for GvHD

151. The largest off-label uses include patients suffering from complications due to Graft-versus-host disease ("GvHD") and solid organ transplant (i.e., heart transplant). GvHD is a complication that can occur after a stem cell or bone marrow transplant in which the newly transplanted material attacks the transplant recipient's body.

152. The Therakos sales representatives, including Relator Johnson, were directed to target bone marrow transplant departments, lung transplant surgeons, pediatric bone marrow transplant surgeons and pediatric children's hospitals that would have little, or no, use for the Product in their practices.

153. Many of these instructions came from Therakos management, including, but not limited to, William Skillman (Vice-President, Worldwide Sales and Marketing) and Ingrid Clark Durfy (General Manager).

154. The instructions to sell off-label continued through 2011. Many of the more recent directives came from Michael Yang (General Manager) and the current management team.

155. In December 2009, Relator Johnson was told that Mr. Yang and George Petagrew (National Sales Director), met with Therakos marketing employees and J&J compliance officers, including Denise Johnson, to discuss and strategize ways in which the sales team could sell "off-label GvHD".

156. Therakos sales representatives, including Relator Johnson, received education in the form of articles and treatises on off-label uses. These materials were sent directly to the Therakos sales representatives, including Relator Johnson, from Mr. Skillman or Therakos management and employees working for him.

157. Therakos sales representatives, including Relator Johnson, were instructed to use these articles and treatises to sell the Product for off-label uses and to convince any doctors or administrators who did not want to use the treatment.

158. Therakos sales representatives, including Relator Johnson, would conference together and review medical education information. Individual sales representatives would be assigned to read an article, make a presentation to the other Therakos sales representatives and prepare an educational program.

159. This "Journal Club" (as it was commonly referred to) was created at Mr. Skillman's direction and administered through senior management at his direction.

160. Similarly, Defendants requested, and expected, the Therakos sales representatives, including Relator Johnson, to prepare annual Sales Plans that included the successful closing of specific off-label organizations.

161. In recent years, Therakos greatly increased the sales quota for Therakos sales representatives, including Relator Johnson. Upon information and belief, some sales quotas were almost doubled compared to that of the prior year.

162. These sales quotas were increased even though Therakos knew that the medical condition for which the Product was FDA-approved (CTCL) was already extremely limited.

163. Not only was there a very small and limited patient population afflicted with CTCL for whom Therakos could target healthcare providers to utilize the Product, but there were no

projections or grounds to support any projections that the percentage and number of these afflicted persons would increase at all, much less *double* over a year's time (or any other future period), so as to reflect the level of increased sales that were imposed on Relator Johnson and other Therakos sales representatives.

164. Relator Johnson and other Therakos sales representatives were directed by Therakos management to expand, by extraordinary margins, the sales of the Product, through a variety of measures intended to promote "off-label" uses of the Product.

165. For example, the New York territory, for almost two years (2012 and 2013), has had virtually no dermatologists treating CTCL with the Product. Rather, the territory has included almost all GvHD business. Despite not having any dermatologists using the Product, Therakos continued to have a sales representative calling on physicians who provided treatment for GvHD, not CTCL. That former sales representative, Christine Relay, was promoted by Therakos as its Global Marketing Manager in September 2013.

2. Therakos Directs Its Sales Representatives to Market the Product for Pediatric Uses

166. One of the major areas targeted for "off-label" growth, and related marketing, was the increased use of the Product by bone marrow transplant doctors and medical institutions specializing in that field. These uses included for the non-FDA approved treatment of GvHD and Solid Organ Transplant Rejection, as well as for controlling or reducing incidents of rejection of transplanted tissues.

167. Another non-FDA approved use for which Defendants pressured account representatives to illegally market the Product was for use in pediatric patients with pediatric bone marrow transplants and CTCL.

168. As early as 2002, Relator Johnson, with the approval of Therakos management, made sales calls to Memorial Sloan Kettering Cancer Center, where he met with and solicited Farid Boulad, MD, who, at the time, was Director of Sloan Kettering's pediatric BMT department.

169. Similarly, in August 2006, Relator Johnson, with the approval of Therakos management, requested funds from Therakos for a presentation to the Columbia University Hospital Department of Pediatrics. *See* Exhibit "E." The program called for David Jacobsohn, M.D., from the Children's Hospital of Chicago, to "present his experience in treating pediatric patients with photopheresis." *See id.* The "BUSINESS BENEFIT[]" for Therakos was that New York Presbyterian/Columbia Hospital was "interested in starting up a pediatric Photopheresis program."

170. Relator Johnson received information from Vanita Sharma, Pharm.D., who is Therakos' Director of Global Advocacy and Education, regarding an incident that occurred in the summer of 2013.

171. An Account Manager from Florida, Daniel DiGirolamo, was speaking to a physician at the University of Alabama-Birmingham Hospital ("UAB"). Upon information and belief, the physician at UAB was a pediatric BMT, whose name is Jill Adamski, MD, PhD.

172. Dr. Adamski asked Mr. DiGirolamo for a photopheresis treatment protocol for **pediatric** GvHD patients.

173. Mr. DiGirolamo called Scott Zanetell, who was also a Therakos Account Manager at the time, and asked him to obtain a pediatric GvHD protocol from one of Mr. Zanetell's customers.

174. Mr. Zanetell obtained the protocol and forwarded it via email to Mr. DiGirolamo, who then forwarded it to Dr. Adamski and copied Dr. Sharma on that email. Mr. Zanetell is now

Therakos' Western Region Business Manager, a promotion he received in July 2013, which was after this situation with Dr. Adamski.

175. Dr. Sharma then called Relator Johnson and told him about this email, as she was concerned there was the potential for an adverse event associated with this usage and she was concerned about being implicated. Dr. Sharma also made her manager, Christian Peters, MD, PhD, Therakos' Chief Medical Officer, aware of this issue.

176. To Mr. Johnson's knowledge neither Mr. Zanetell, nor Mr. DiGirolamo, were ever warned or rebuked for their conduct.

177. Additionally, upon information and belief, Therakos' largest growth customer over the past two years has been Hoxworth Blood Center (http://www.hoxworth.org/) in Cincinnati, Ohio.

178. The Hoxworth Blood Center at the University of Cincinnati College of Medicine ("Hoxworth") grew from approximately 213 treatments in 2011 to more than 1,750 treatments in 2013.

179. Therakos' Account Manager for Hoxworth is Eric Keener.

180. Relator Johnson believes that the Hoxworth account is almost entirely a pediatric account. Upon information and belief, Relator Johnson states that Hoxworth has only two patients being treated for the FDA-approved indication of CTCL, but the rest of the treatments are for ***pediatric*** GvHD.

181. Off-label, non-approved use of Therakos photophersis is dangerous for pediatric patients.

182. For example, this link (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=3239650)

describes a 6-year old patient being treated for Acute GvHD who had a seizure while receiving photopheresis.

183. At the sales level, Relator reports that there is considerable concern about the quality and safety of the Cellex instrument.

3. Therakos Targets Certain Healthcare Institutions For Sales

184. Relator Johnson can identify numerous specific off-label organizations that were targeted by Therakos sales representatives with the approval of Defendants' management.

185. For example, Johns Hopkins University Hospital ("Hopkins") was doing no photopheresis in 2001. However, Therakos sales representatives began to solicit Johns Hopkins in late 2001 for CTCL treatment, as well as GvHD. For example, although Daniel N. Sauder, M.D., was the Chairman of the Department of Dermatology at Hopkins, Relator Johnson was directed to solicit him, as well as other doctors at Hopkins, including Richard Jones, M.D. (specialized in bone marrow transplant, Chief of department), Georgia B. Vogelsgang, M.D. (expert in GVHD) and F. Javier Bolanos Meade, M.D. (specialized in bone marrow transplant).

186. Most of the pressure and instructions to Relator Johnson and other Therakos sales representatives came directly from Mr. Skilman, Ms. Durfy, Mr. Yang and/or Kate Hayes (Regional Business Manager, East Coast). Further, Therakos managers that were personally appointed by Mr. Yang directed Relator Johnson and other Therakos sales representatives.

187. Relator Johnson and other Therakos sales representatives entered information into the company's Siebel sales database, which was used to record data such as the doctors or other medical providers that the sales representatives had contacted or called upon, and any specific notes or comments that the sales representative thought was relevant and helpful about the doctors or healthcare providers, often including the nature of their medical practice.

188. However, Mr. Yang altered the method by which Relator Johnson and other Therakos sales representatives entered information to help conceal Defendants' illegal, "off-label" marketing conduct. For example, Therakos management removed the "free text" section of the company's Siebel database to prevent sales representatives from continuing to note information relating to off-label sales and promotion.

189. Upon information and belief, a Therakos sales representative was told by Mr. Yang that the reason for purging or keeping such data from this sales and customer-related database was due to a lesson learned when he was managing another J&J company that was the subject of government probes for unlawful conduct, in which the government used audits of the sales and customer databases to elicit evidence indicating from the identities and practice areas of the medical providers listed therein to help prove its claims against the J&J company, and that Mr. Yang would not allow that to occur again with respect to Therakos and its sales practices

190. Several of the Therakos sales representatives, including Relator Johnson, expressly objected to engaging in the promotion of the Product for the above-described "off-label" uses that comprised the main basis and strategy for Defendants' new sales targets and plan for the Product Indeed, Relator Johnson called the J&J compliance hotline to complaint about unreasonable sales quotas, which could only be achieved through off-label promotion.

B. Therakos Violates Promotion and Marketing Regulations at Several Promotional Events

191. During the relevant time period, J&J, and thus Therakos, had in place certain policies and procedures relating to healthcare compliance issues with CMEs and professional programs. None of these policies and procedures were adhered to by Therakos management or its sales representatives

1. Selling Directly to Physicians at Professional/CME Events

192. One of Relator Dr. Strobl's responsibilities with Therakos was to develop, organize and/or present at clinical symposia, Professional Society meetings and CME programs to other doctors (collectively, the "Professional/CME Events"). These clinical symposia and Professional/CME Events often involved several clinical specialties including bone marrow transplant, solid-organ transplant, oncology, gastroenterology, rheumatology, and dermatology.

193. However, Relator Dr. Strobl, and, to a lesser extent, Relator Johnson, can confirm that Therakos management ignored these regulations and knowingly permitted, and encouraged, Relator Dr. Strobl to present such clinical symposia and Professional/CME Events in violation of the internal policies and external laws.

194. For example, in February 2007, Relator Dr. Strobl coordinated an event for Relator Johnson at the annual Dermatology Nurses Association meeting. The Professional/CME Event, entitled "Clinical Utility of Extracorporeal Photophersis (ECP) in Immune Mediated Diseases" (the "ECP Program"), included the following issues:

a. The ECP Program had no documented, specific, unsolicited request from a healthcare provider; the event was simply run as a promotional sales program.

b. The Director of Scientific Affairs was present at the ECP Event, when field-based medical staff were not to engage in promotional activity.

c. The presentation discussed off-label topics (including GvHD and transplant rejection), without specific solicitation from healthcare providers for the off-label topics discussed.

d. Unauthorized attendees were present at ECP Event.

195. Dennis DeCola, who was Therakos' compliance officer, was present at the meeting and reviewed and approved the slide presentation before the program.

196. Dr. Strobl eventually was issued a formal verbal warning by Defendants for the ECP Program resulting in his termination. Mr. DeCola received a verbal warning, but, upon further information, no further sanction or punishment.

197. Similarly, in February 2006, at the Tandem Bone Marrow Transplant meeting in Honolulu, Hawaii, Therakos held several events and dinners, as well as a Lunch Symposia to discuss off-label uses of the Product with bone marrow transplant surgeons and nurses.

2. Relator Dr. Strobl Is Instructed to Sells Directly to Physicians

198. One of Dr. Strobl's many responsibilities as the Director of Medical Affairs was to respond to questions concerning off-label uses of the Therakos product *when requested by physicians.*

199. However, from almost his first day with Therakos, Dr. Strobl was directed to promote and give presentations to physicians all over the United States about off-label uses.

200. Several emails from Amy Gorman, who was Therakos' Northwest Account Manager, to Relator Dr. Strobl and other Therakos management, including Dennis DeCola, illustrate the pervasive belief that sales representatives were permitted to schedule and organize promotional events for Therakos involving off-label uses.

201. These meetings and/or presentations for and to doctors were set up almost exclusively at the request of the Therakos' sales representatives, not the physicians.

202. A sales presentation produced for Dr. Strobl's use at one of these meetings is attached hereto as Exhibit D.

203. This presentation refers regularly to various applications of the Therakos product to GvHD uses, as well as organ transplant related conditions. *See id.* at pages 19, 21-24. The Therakos product was not, and has never been, approved for treatment of GvHD, or any related

organ transplant transfer or bone marrow transplant condition. In fact, one slide lists the various GvHD conditions for which the Therakos product was being promoted:

a. Prevention of GvHD;

b. Acute GvHD;

c. Chronic GvHD; and

d. Pediatric GvHD.

See id. at 24.

204. The presentation also contains several slides discussing the use of ECP in ***pediatric*** patients with GvHD. The Therakos product has never been approved for any pediatric use, even one related to CTCL. *See id.* at 42-45.

3. Therakos Uses Sales Programs to Improperly Market Its Products and Services

205. Relator Dr. Strobl was privy to many of the sales plans and activities being introduced and developed by the Therakos management team. Indeed, Dr. Strobl was a member of the management team from 2006 through 2007.

206. For example, in late 2003, at Sales Meeting in Houston, Texas, where plans for 2004 were being developed, the company blatantly referred to GvHD as one if its goals.

207. The presentation to the Therakos sales team included a discussion of GvHD and referred to it as "Key Learning."

208. Later in the presentation, Therakos stated that two of its "Initiatives" were to "[i]ncrease GvHD speaker programs" and "establish in-territory preceptorship programs in GvHD, CTCL, Crohns, RA."

209. In or around 2006, Therakos management introduced a sales program referred to as "WAVE."

210. The object of WAVE was to "implement a focused, targeted commercialization plan for the next 90 days, designed to drive sales velocity with the strong assets we have."

211. At the time of WAVE, Therakos' sales were only approaching $46.5 million, while forecast had called for a $49.2 million future.

212. Some of the goals and selling methods established by Therakos management included the following, which prominently mention GvHD although Therakos' ECP system was not approved for use in GvHD situations:

a. "**Objective: ECP becomes top-of-the-mind among physicians who treat CTCL or GvHD**" (emphasis in original); and

b. "**Selling Tools** – 3 primary selling aids launched: CTCL, GvHD, ECP Competition" (emphasis in original);

213. Similarly, an August 2006 sales strategy meeting required Relator Dr. Strobl to create a GvHD Advisory Board to drive sales growth.

214. The idea to create an "impactful" GvHD Advisory Board was developed by General Manager Durfy and Vice-President of Sales Brad Adams.

C. Therakos' New Device Is Failing At An Alarming Rate

215. In March 2009, FDA approved the THERAKOS™ CELLEX™ Photophersis System ("Cellex") for the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that are unresponsive to other forms of treatment. *See* http://www.investor.jnj.com/textonly/releasedetail.cfm?ReleaseID=372242.

216. Therakos immediately began to market the newer Cellex machines as replacements for the the older Uvadex machines.

217. However, the Cellex machines have consistently and regularly failed over the past several months, leading to numerous incidences of repeated and excessive alarms and leaking or defective kits.

218. Indeed, James Wheeler, Therakos' Eastern Region Sales Manager, told Relator Johnson, in November 2013, that Therakos was having a Cellex "nightmare."

219. For example, on February 25, 2014, both Cellex machines at the Perelman Center at the Hospital of the University of Pennsylvania malfunctioned. One machine "exploded" and a patient's fully-connected blood sample was completely lost. *See* attached photographs of the Cellex machine post-explosion, as Exhibit F. Individuals at the Perelman Center has been complaining about the Cellex machines, including repeated alarms and malfunctioning components, for months.

220. Similarly, numerous other hospitals and blood centers have experienced similar problems with the Cellex machine:

a. in late February 2014, Christiana Hospital in Delaware complained that its Cellex machine was constantly malfunctioning and creating problems for the staff;

b. Massachusetts General Hospital in Boston has complained of exploding bowls and treatment failures with the hospital's Cellex machine;

c. Robert Wood Johnson Hospital, New Brunswick, New Jersey, reported that it had several malfunctions in the latter half of 2013 and the beginning of 2014;

d. in November 2013, Therakos responded to complaints from The Children's' Hospital of Philadelphia that its Cellex machine was experiencing numerous Red Cell Pump Alarms, System Pressure Alarms and Return Pressure Alarms;

e. Joselyn Gonzalez, MD, FACP, who is the Director of Photophersis and Medical Director for the Family Health Center at Morristown Medical Center in Morristown, New Jersey, sent a list of "instrument problems" with two Cellex machines at the hospital to Relator in August 2013. This list included four instances of a particular machine's centrifuge stopping in the middle of a treatment. Relator Johnson forwarded this list to a number of individuals at Therakos, including Mr. Wheeler, the Eastern Region Business Manager.

221. Relator alleges, upon information and belief, that there have been hundreds of incidents of defective kits reported to Therakos' Technical Support hotline. While not all of the incidents have resulted in a broken bowl, *see* example of a "broken or exploded bowl" attached photograph as Exhibit F, these incidents do make reuse of the patient's blood impossible.

222. Once the kit is compromised, the patient's blood cannot be returned to the individual.

223. The primary health danger is that many of the patients utilizing the Therakos' Cellex machine for GvHD are already immuno-compromised and have a low hematocrit, so not being able to re-use the blood or return it to the individual reduces it even further. Further, it greatly increases the risk of infection.

224. A number of the Cellex machines experiencing malfunctions are located in pediatric hospitals or institutions across the country.

225. Upon information and belief, Relator Johnson believes that Therakos has known about, and been in possession, of a kit design change that would resolve the continuous problems with the Cellex machine.

226. According to Relator Johnson, this design change would solve the problem of the "red cell pump alarm" which is causing a great many of the problems with the Cellex.

227. Relator Johnson was told that numerous members of Therakos management, including Roy Davis, Nick Valeriani, Ingrid Clark Durfy and Michael Yang, were aware of the solution, but would not provide funding for implementation because it would cost too much and would delay the launch of the Cellex system.

228. In fact, just recently, Dennis Briggs, Therakos' Vice-President of Research and Development, resubmitted this design change to the FDA for approval; Mr. Briggs is confident that this "fix" will solve several of the issues.

229. Upon information and belief, Relator alleges that Defendants OCD and J&J knew of the myriad manufacturing issues with the Cellex machines for several years, but would not provide their subsidiary, Therakos, with adequate funds to fix or resolve the issue. Relator was recently informed of this fact by Jake Hardin, the Vice-President for Quality and Reliability Control at Therakos.

D. Fraudulent Conduct Continues, and Is Encouraged, by Mallinckrodt

230. Mallinckrodt purchased Therakos from The Gores Group in September 2015 for approximately $1.33 billion.

231. Much of the same conduct complained of above that occurred when Therakos was owned by both the J&J Defendants and The Gores Group continues today under Mallinckrodt's ownership.

232. On or about January 26, 2016, Relator Johnson was provided with a list of physicians (the "January 2016 Physician List") by his superiors at Therakos. Relator Johnson

received the January 2016 Physician List from his manager, Erin Waverley, Therakos' East Regional Business Manager.

233. Utilization of the January 2016 Physician List by Therakos Territory Sales Managers was described as a key initiative of Therakos' new management's sales strategy.

234. Relator Johnson was instructed to contact the providers on the January 2016 Physician List and promote ECP.

235. Relator believes that similar lists were sent to other Therakos Territory Managers with comparable instructions - Contact any provider on the list who was not familiar to them. A PowerPoint presentation ("TM Target Database Rollout 1-25-16") that accompanied the January 2016 Physician List included the instruction - "1. Find the names of people who aren't familiar to you 2. Qualify the names you identified 3. Validate at least 10 names . . .."

236. Relator Johnson was told that the physicians on the January 2016 Physician List treat CTCL. However, Relator identified at least eight (8) bone marrow transplant (BMT) physicians on the January 2016 Physician List provided to Relator:

- Jakub Svoboda, MD - Professor in the Division of Hematology/Oncology, at the Abramson Cancer Center of the University of Pennsylvania
- Scott D. Rowley, MD - Chief of John Theurer Cancer Center's Blood and Marrow Stem Cell Transplantation Division, Hackensack, NJ
- Michele L. Donato, MD – Chief, Adult Blood and Marrow Stem Cell Transplantation Program, John Theurer Cancer Center, Hackensack, NJ
- Alan P. Zausner Skarbnik, MD – Hematologist/Oncologist, Chief of Chronic Lymphocytic Leukemia Program, John Theurer Cancer Center, Hackensack, NJ
- Witold Rybka, MD –
- Arnob Banerjee, MD, PhD – Assistant Professor of Medicine, Hematology/Oncology, University of Maryland Medical Center
- Stephen Schuster, MD – Director, Lymphoma Translational Research, Abramson Cancer Center of the University of Pennsylvania

- James K. Mangan, MD, PhD - Assistant Professor of Clinical Medicine, Hematology/Bone Marrow Transplant, Abramson Cancer Center Perelman Center for Advanced Medicine

237. Relator is familiar with Dr. Donato and Dr. Rowley from the John Theurer Cancer Center and has never known them to treat a CTCL patient.

238. Moreover, all of the physicians identified by Relator, except Dr. Banerjee, are listed on the National Marrow Donor program website as attending physicians in their respective BMT programs at each hospital.

239. Relator Johnson believes that the January 2016 Physician List was created and distributed by Therakos' marketing department, specifically Christine Relay (Therakos' Global Marketing Manager since September 2013) who was a Therakos Territory Manager at one time.

240. When she was a Territory Manager, Ms. Relay's territory included Hackensack University Medical Center ("HUMC"); Relator Johnson knows that Ms. Relay is familiar with Dr. Donato and Dr. Rowley. Ms. Relay is also very aware that HUMC is one of the largest photopheresis centers in the country and that it treats many more patients suffering from GvHD then CTCL.

241. Relator Johnson also had responsibility for the HUMC account for several years and he only remembers HUMC treating one CTCL patient during that entire period.

242. Similarly, Donna Weise, a Therakos Territory Manager who covers the Southwest U.S. territory, informed Relator Johnson that there were BMT providers on the list she was provided in January 2016.

243. It would have been very easy for Therakos to "clean" or "vet" the January 2016 Physician List to exclude BMT physicians; moreover, Therakos could have distributed the list with an instruction stating that any BMT provider on the list should be removed.

244. In or around February 2016, Regional Business Manager Waverly informed Relator Johnson that Mallinckrodt was very concerned about Therakos' flat sales in 2015 and 2016. Ms. Waverly also told Relator Johnson that Scott Zanetell, Therakos' National Sales Manager, was receiving a great deal of pressure from new management to increase the sales numbers immediately.

245. Hollie Huggins, a Therakos Territory Manager who is based in Texas, told Relator Johnson that Chris Paino, Therakos' Western Region Manager for Therakos, was aware that many of the physicians on the January 2016 Physician List are BMT providers.

246. Ms. Huggins also told Relator that National Sales Manager Zanetell was aware that many of the physicians on the January 2016 Physician List are BMT providers.

247. In or around March 2016, Relator discovered additional BMT physicians on the January 2016 Physician List. For example, during the week of March 21-25, 2016, Relator made sales calls on Stefan Barta, MD, MS, MRCP, at Fox Chase-Temple University Hospital Bone Marrow Transplant Program, and Seyfettin Alpdogan, MD, at Thomas Jefferson University's BMT program. Although Relator was not able to speak with either of these physicians during the visits, he did record the information that he had called on them in Therakos' Customer Relationship Management ("CRM") software because a sales representative's performance metrics is based on calling on physicians on the January 2016 Physician List.

248. On or about April 12, 2016, Relator Johnson again explained to Regional Business Manager Waverley that a large number of physicians included on the January 2016 Physician List were BMT providers. Ms. Waverly responded that the list came from "management" and that there was nothing she could do about it.

249. Although Relator Johnson has reported that several of the physicians on the January 2016 Physician List should not be included, no changes have been made.

250. On or about May 23, 2016, Relator Johnson participated in a national sales call, led by National Sales Director Zanetell. All of Therakos' sales representatives and managers participated in the call.

251. Zanetell told the Therakos sales representatives that Mallinckrodt's "Finance Officer" (who is located in Mallinckrodt's U.S. headquarters in St. Louis, MO) had been asking him a lot of questions about why sales are off. At the time, the weekly sales goal for kit sales was 1,500 kits. According to East Region Business Manager Waverly, the company barely sold 1,100 kits during the week of May 9-13. During the call, Zanetell inquired into the sales with the sales team, and asked if there any large orders were expected.

252. One of the Territory Managers, Eric Keener (covers Ohio), stated on the call that some of his accounts are using Velcade (a type of chemotherapy) to reduce the amount of GvHD. Territory Manager Weise stated that several of her accounts are seeing less GvHD than they have in the past because doctors and hospitals are getting better at performing transplants.

253. Upon information and belief, Therakos' decreased sales demonstrate that if ECP is not being actively promoted for GvHD, the company's sales are going to decrease significantly. It also confirms that the viability/profitability of Therakos' ECP business has always relied on off-label promotion.

254. Also, in a call on May 2, 2016, Zanetell told the Therakos sales representatives that Mallinckrodt expects high double-digit growth.

255. Relator Johnson attended Therakos' National Sales Meeting in Las Vegas in February 2016.

256. Therakos currently has 12 sales representatives, or Territory Managers. Therakos announced that the target kit goal for 2016 is approximately 80,500 kit units. This is the national sales number, which the sales team must achieve in order to be paid a bonus. This represents a 10% increase over 2015's sale number.

257. During the meeting, Relator spoke with two other Therakos Territory Managers – Ben Black and Eric Keener. Both Territory Managers have been with Therakos for several years, including when Defendant J&J owned Therakos. Both of them independently shared with Relator that they have called, and continue to call, on Bone Marrow Transplant surgeons.

258. In December 2015, Relator Johnson attended a meeting with Jennifer (Jenni) Anderson, RN, HP (ASCP), the Clinical Coordinator of the Apheresis Unit at the Medical College of Virginia ("MCV") in Richmond, VA. Ms. Anderson told Relator that MCV has treated pediatric patients using ECP.

259. In a previous conversation relating to MCV-VCU, Ms. Anderson told Relator that Ben Black, a Therakos Territory Manager, had called on John M. McCarty, M.D., Medical Director, Bone Marrow Transplant Program at Virginia Commonwealth University's Massey Cancer Center in Richmond, VA, sometime in early 2015/late 2014. After this meeting, the number of patient treatments referred by VCU physicians to the MCV Apheresis Unit increased dramatically.

260. Dr. McCarty referred 33 patients to the Apheresis Unit.

261. In 2015, the sales at MCV were tracking almost double what had been sold in 2014.

262. Notes prepared by Territory Manager Black state that Therakos needed to maintain "strong relationships" with key doctors, including Dr. McCarty. However, there is no reason for Therakos to be in contact with Dr. McCarty, as he has nothing to do with the Apheresis Unit/ECP

program other than to refer patients for treatment. Likely, the reason for Mr. Black to contact Dr. McCarty was to promote the use of photopheresis for treating GvHD. Thus, upon information and belief, as recently as 2015, despite this investigation, Territory Manager Black was continuing to contact BMT physicians.

263. Relator is also aware that Territory Manger Ben Black called on Children's National Medical Center in Washington, D.C. sometime in 2015.

COUNT I
False Claims Act - Presentation of False Claims
31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A), as amended in 2009

264. The allegations of the preceding paragraphs are realleged as if fully set forth below.

265. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information which supported claims to CMS, and Federal Programs, with actual knowledge of the falsity of the information that supported these claims, cause, and continues to be causing, the use of false or fraudulent materials or information to support claims paid by the government.

266. Through the acts described above and otherwise, Defendants and their agents and employees knowingly presented or caused to be presented to the United States Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

267. The United States of America, unaware of the falsity of the claims and statements made by Defendants, and in reliance on the accuracy of these claims and statements, paid and is continuing to pay or reimburse claims for Defendants' pharmaceuticals for patients enrolled in federally-funded medical care programs.

268. As a direct result of Defendants' actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

COUNT II
False Claims Act - Making or Using False Records or Statements to Cause Claim to be Paid
31 U.S.C. § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B), as amended in 2009

269. The allegations of the preceding paragraphs are realleged as if fully set forth below.

270. Through the acts described above and otherwise, Defendants and their agents and employees knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2), and, as amended, 31 U.S.C. § 3729(a)(1)(B), in order to get false or fraudulent claims paid and approved by the United States Government.

271. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and is continuing to pay or reimburse claims for Defendants' pharmaceuticals for patients enrolled in federally-funded medical care programs.

272. As a direct result of Defendants' actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

COUNT III
False Claims Act – Conspiracy
31 U.S.C. § 3729(a)(3), 31 U.S.C. § 3729(a)(1)(C) as amended in 2009

273. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

274. Through the acts described above and otherwise, Defendants entered into a conspiracy or conspiracies to defraud the United States by getting false and fraudulent claims

allowed or paid in violation of 31 U.S.C. § 3729(a)(3), and as amended 31 U.S.C. § 3729(a)(1)(C). Defendants also conspired to omit disclosing or to actively conceal facts which, if known, would have reduced Government obligations to it or resulted in repayments from it to Government programs.

275. Defendants, its agents, and its employees have taken substantial steps in furtherance of those conspiracies, *inter alia*, by preparing false records, by submitting claims for reimbursement to the Government for payment or approval, and by directing its agents and personnel not to disclose and/or to conceal its fraudulent practices.

276. The United States, unaware of Defendants' conspiracy or the falsity of the records, statements and claims made by Defendants, its agents, and employees, and as a result thereof, has paid and continues to pay millions of dollars that it would not otherwise have paid. Furthermore, because of the false records, statements, claims, and omissions by Defendants and their agents and employees, the United States has not recovered federal funds from the Defendants that otherwise would have been recovered.

COUNT IV
False Claims Act - Making or Using False Records or Statements to Conceal, Avoid and Decrease Obligation to Repay Money
31 U.S.C. § 3729(a)(7), 31 U.S.C. § 3729(a)(1)(G), as amended in 2009

277. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

278. Through the acts described above and otherwise, in violation of 31 U.S.C. § 3729(a)(7), and, as amended, 31 U.S.C. § 3729(a)(1)(G), Defendants and their agents and employees knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, and decrease Defendants' obligation to repay money to the United States Government that Defendants improperly or fraudulently received. Defendants also failed to

disclose material facts that would have resulted in substantial repayments to the United States Government.

279. As a direct result of Defendants' actions as set forth in the Complaint, the United States of America has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

280. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, Defendants knowingly made, used, or caused to be made or used, false or fraudulent records or statements, to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States of America and the *Qui Tam* States in violation of 31 U.S.C. §3729(a)(7).

281. As a direct result of Defendants' actions as set forth in the Complaint, the United States of America, and the *Qui Tam* States, have been, and may continue to be, severely damaged.

COUNT V
California False Claims Act
Cal. Gov't Code § 12651 *et seq.*

282. The allegations of the preceding paragraphs are realleged as if fully set forth below.

283. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651 *et seq.*

284. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the California Medicaid Program (i.e., Medi-Cal) false or fraudulent claims for the improper payment or approval of prescriptions for its above-mentioned pharmaceuticals and used false or fraudulent records to accomplish this purpose.

285. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

286. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VI
Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-4-304 *et seq.*

287. The allegations of the preceding paragraphs are realleged as if fully set forth below.

288. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act. Colo. Rev. Stat. § 25.5-4-304 *et seq.*

289. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Colorado Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions and used false or fraudulent records to accomplish this purpose.

290. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

291. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VII
Connecticut False Claims Act
Conn. Gen. Stat. § 17b-301a *et seq.*

292. The allegations of the preceding paragraphs are realleged as if fully set forth below.

293. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301 *et seq.*

294. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to an officer or employee of the state and the Connecticut Medicaid Program false or

fraudulent claims for the improper payment or approval of prescriptions for its above-mentioned drugs and used false or fraudulent records to accomplish this purpose.

295. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

296. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT VIII
Delaware False Claims Act
Del. Code Ann. tit. 6, § 1201 *et seq.*

297. The allegations of the preceding paragraphs are realleged as if fully set forth below.

298. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit. 6, § 1201 *et seq.*

299. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Delaware Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for its pharmaceuticals mentioned above and used false or fraudulent records to accomplish this purpose.

300. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

301. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT IX
Florida False Claims Act
Fla. Stat. Ann. § 68.081 *et seq.*

302. The allegations of the preceding paragraphs are realleged as if fully set forth below.

303. This is a claim for treble damages and civil penalties under the Florida False Claims Act. Fla. Stat. Ann. § 68.081 *et seq.*

304. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Florida Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for its pharmaceutical and used false or fraudulent records to accomplish this purpose.

305. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

306. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT X
Georgia False Medicaid Claims Act
Ga. Code Ann. § 49-4-168 *et seq.*

307. The allegations of the preceding paragraphs are realleged as if fully set forth below.

308. This is a claim for treble damages and civil penalties under the False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

309. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Georgia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for its pharmaceuticals and used false or fraudulent records to accomplish this purpose.

310. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

311. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XI
Hawaii False Claims Act
Haw. Rev. Stat. § 661-22 *et seq.*

312. The allegations of the preceding paragraphs are realleged as if fully set forth below.

313. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-22 *et seq.*

314. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for its pharmaceuticals described above and used false or fraudulent records to accomplish this purpose.

315. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

316. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XII
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. 175/1 *et seq.*

317. The allegations of the preceding paragraphs are realleged as if fully set forth below.

318. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act. 740 Ill. Comp. Stat. 175/1 *et seq.*

319. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Illinois Medicaid Program false or fraudulent claims for the improper payment or

approval of prescriptions for the Product mentioned above and used false or fraudulent records to accomplish this purpose.

320. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

321. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIII
Indiana False Claims and Whistleblower Protection
Burns Ind. Code Ann. § 5-11-5.5-1 *et seq.*

322. The allegations of the preceding paragraphs are realleged as if fully set forth below.

323. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Law. Burns Ind. Code Ann. § 5-11-5.5-1 *et seq*.

324. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Indiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product mentioned above and used false or fraudulent records to accomplish this purpose.

325. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

326. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIV
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. Ann. § 46:437.1 *et seq.*

327. The allegations of the preceding paragraphs are realleged as if fully set forth below.

328. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law. La. Rev. Stat. Ann. § 46:439.1 *et seq*.

329. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and knowingly used false or fraudulent records to accomplish this purpose.

330. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

331. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XV
Maryland False Health Claims Act
Md. Code Ann., Health-Gen. §2-601 *et seq.*

332. The allegations of the preceding paragraphs are realleged as if fully set forth below.

333. This is a claim for treble damages and civil penalties under the Maryland False Claims Act, Md. Code Ann., Health-Gen. §2-601 *et seq*.

334. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Maryland Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

335. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

336. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVI
Massachusetts False Claims Act
Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

337. The allegations of the preceding paragraphs are realleged as if fully set forth below.

338. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act. Mass. Ann. Laws ch. 12, § 5(A) *et seq.*

339. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

340. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

341. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVII
Michigan Medicaid False Claim Act
Mich. Comp. Laws §400.601 *et seq.*

342. The allegations of the preceding paragraphs are realleged as if fully set forth below.

343. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act. MCL § 400.601 *et seq*.

344. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Michigan Medicaid Program false or fraudulent claims for the improper payment

or approval of prescriptions for Defendants and used false or fraudulent records to accomplish this purpose.

345. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

346. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XVIII
Minnesota False Claims Act
Minn. Stat. § 15C.01 *et seq.*

347. The allegations of the preceding paragraphs are realleged as if fully set forth below.

348. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act. Minn. Stat. § 15C.01 *et seq.*

349. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

350. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

351. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XIX
Montana False Claims Act
Mont. Code Ann. §17-8-401 *et seq.*

352. The allegations of the preceding paragraphs are realleged as if fully set forth below.

353. This is a claim for treble damages and civil penalties under the Montana False Claims Act. Mont. Code Ann. § 17-8-401 *et seq*.

354. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Montana Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

355. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

356. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XX
Nevada False Claims Act
Nev. Rev. Stat. § 357.010 *et seq.*

357. The allegations of the preceding paragraphs are realleged as if fully set forth below.

358. This is a claim for treble damages and civil penalties under the Nevada False Claims Act. Nev. Rev. Stat. § 357.010 *et seq.*

359. The allegations of the preceding paragraphs are realleged as if fully set forth below. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Nevada Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for insulin pens and used false or fraudulent records to accomplish this purpose.

360. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

361. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXI
New Hampshire Medicaid Fraud and False Claims Law
N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

362. The allegations of the preceding paragraphs are realleged as if fully set forth below.

363. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law. N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

364. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the previously mentioned Product and used false or fraudulent records to accomplish this purpose.

365. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

366. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXII
New Jersey False Claims Act
N.J. Stat. § 2A:32C-1 *et seq.*

367. The allegations of the preceding paragraphs are realleged as if fully set forth below. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act. N.J. Stat. § 2A:32C-1 *et seq.*

368. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be

presented to the New Jersey Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses and used false or fraudulent records to accomplish this purpose.

369. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

370. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIII
New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-1 *et seq.*

371. The allegations of the preceding paragraphs are realleged as if fully set forth below.

372. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act. N.M. Stat. Ann. § 27-14-1 *et seq.*

373. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

374. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

375. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIV
New York False Claims Act
N.Y. State Fin. Law § 187 *et seq.*

376. The allegations of the preceding paragraphs are realleged as if fully set forth below.

377. This is a claim for treble damages and civil penalties under the New York False Claims Act. N.Y State Fin. Law § 187 *et seq.*

378. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the New York Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for off-label uses and used false or fraudulent records material to a false or fraudulent claim to accomplish this purpose.

379. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

380. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXV
North Carolina False Claims Act
N.C. Gen. Stat. § 1-605 *et seq.*

381. The allegations of the preceding paragraphs are realleged as if fully set forth below.

382. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Stat. § 1-605 *et seq*.

383. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

384. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

385. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVI
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63 § 5053 *et seq.*

386. The allegations of the preceding paragraphs are realleged as if fully set below.

387. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 § 5053 *et seq.*

388. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

389. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

390. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVII
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 *et seq.*

391. The allegations of the preceding paragraphs are realleged as if fully set forth below.

392. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act. R.I. Gen. Laws § 9-1.1-1 *et seq.*

393. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for the improper

payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

394. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

395. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXVIII
Tennessee False Claims Act, Tenn. Code § 4-18-101 *et seq.*
Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

396. The allegations of the preceding paragraphs are realleged as if fully set forth below.

397. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, and the Tennessee False Claims Act. Tenn. Code Ann. § 71-5-181 *et seq.*

398. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Tennessee Medicaid Program (i.e. TennCare) false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

399. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

400. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXIX
Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

401. The allegations of the preceding paragraphs are realleged as if fully set forth below.

402. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act. Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

403. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly made a claim to the Texas Medicaid Program for a product that has been adulterated, debased, or mislabeled, or that is otherwise inappropriate, and caused to be presented to the Texas Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions and used false or fraudulent records to accomplish this purpose.

404. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

405. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.1 *et seq.*

406. The allegations of the preceding paragraphs are realleged as if fully set forth below.

407. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act. Va. Code Ann. §8.01-216.1 *et seq.*

408. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Virginia Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

409. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

410. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXI
Wisconsin False Claims Act
Wis. Stat. § 20.931 *et seq.*

411. The allegations of the preceding paragraphs are realleged as if fully set forth below.

412. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act. Wis. Stat. § 20.931 *et seq*.

413. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

414. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

415. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXII
District of Columbia False Claims Act
D.C. Code § 2-308.14 *et seq.*

416. The allegations of the preceding paragraphs are realleged as if fully set forth below.

417. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act. D.C. Code § 2-308.03 *et seq*.

418. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non-reimbursable claims described above, Defendants knowingly caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for the improper

payment or approval of prescriptions for off-label uses of the Product described above and used false or fraudulent records to accomplish this purpose, and conspired with each other to effectuate this plan.

419. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

420. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXIII
The City of Chicago False Claims Act
Chicago Municipal Code, § 1-22-010 *et seq.*

421. The allegations of the preceding paragraphs are realleged as if fully set forth below.

422. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act. Chicago Municipal Code § 1-22-010 *et seq.*

423. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non- reimbursable claims described above, Defendants knowingly caused to be presented to t he Chicago Department of Public Health false or fraudulent claims for the improper payment or approval of prescriptions for the Product described above and used false or fraudulent records to accomplish this purpose.

424. The City of Chicago Department of Public Health, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

425. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXIV
New York City False Claims Act
New York City Adm. Code, § 7-801 *et seq.*

426. The allegations of the preceding paragraphs are realleged as if fully set forth below.

427. This is a claim for treble damages and civil penalties under the New York False Claims Act, New York Adm. Code, § 7-801.

428. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non- reimbursable claims described above, Defendants knowingly caused to be presented to New York City false or fraudulent claims for the improper payment or approval of prescriptions for the Product identified above and used false or fraudulent records to accomplish this purpose.

429. The New York City Health and Hospitals Corporation, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

430. By reason of these payments, the New York City Health and Hospitals Corporation has been damaged, and continues to be damaged in a significant amount.

COUNT XXXV
Washington Medicaid Fraud False Claims Act
Wash. Rev. Code Ann. § 48.80.010 *et seq.*

431. The allegations of the preceding paragraphs are realleged as if fully set forth below.

432. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act Wash. Rev. Code Ann. § 48.80.010 *et seq*.

433. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non- reimbursable claims described above, Defendants knowingly caused to be presented to Washington false or fraudulent claims for the improper payment or approval of

prescriptions for the Product identified above and used false or fraudulent records to accomplish this purpose.

434. The Washington Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.

435. By reason of these payments, the Washington Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT XXXVI
Iowa False Claims Act
Iowa Code Ann. § 685.1 *et seq.*

436. The allegations of the preceding paragraphs are realleged as if fully set forth below.

437. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. § 685.1 *et seq.*

438. Defendant, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Iowa.

439. By virtue of the off-label and false marketing and promotion of the Product, and submissions of non- reimbursable claims described above, Defendants knowingly caused to be presented to Washington false or fraudulent claims for the improper payment or approval of prescriptions for the Product identified above and used false or fraudulent records to accomplish this purpose.

440. The Iowa Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

441. By reason of these payments, the Iowa Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relators Michael Johnson and Frank J. Strobl, M.D., Ph.D., request that judgment be entered against the Defendants, ordering that:

a. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*;

b. Defendants pay not less than $10,781.40 and not more than $21,562.80 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of the Defendants' actions;

c. Relators be awarded the maximum "Relator's share" allowed pursuant to 31 U.S. C. § 3730(d) and similar provisions of the state false claims acts;

d. Relators be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S. C. § 3730(d) and similar provisions of the state false claims acts;

e. Relators be provided with injunctive or equitable relief, as may be appropriate, to prevent further harm to himself and to prevent the harm to others and the public that may be caused by Defendants' retaliation against whistleblowers;

f. Relators be awarded all litigation costs, expert fees, and reasonable attorneys' fees incurred as provided pursuant to 31 U.S.C. § 3730(h) and other applicable law;

g. Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

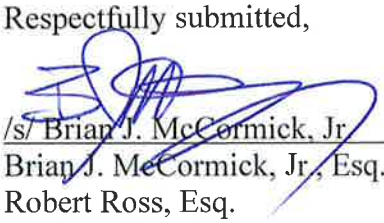
h. Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

i. The United States, the Individual States, and Relators recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Relators hereby demand a trial by jury.

Respectfully submitted,



/s/ Brian J. McCormick, Jr.

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Attorneys for Relators

Dated: December 9, 2016

EXHIBIT A

Extracorporeal Photopheresis (ECP)

Therakos℠
Immune Cell Therapy

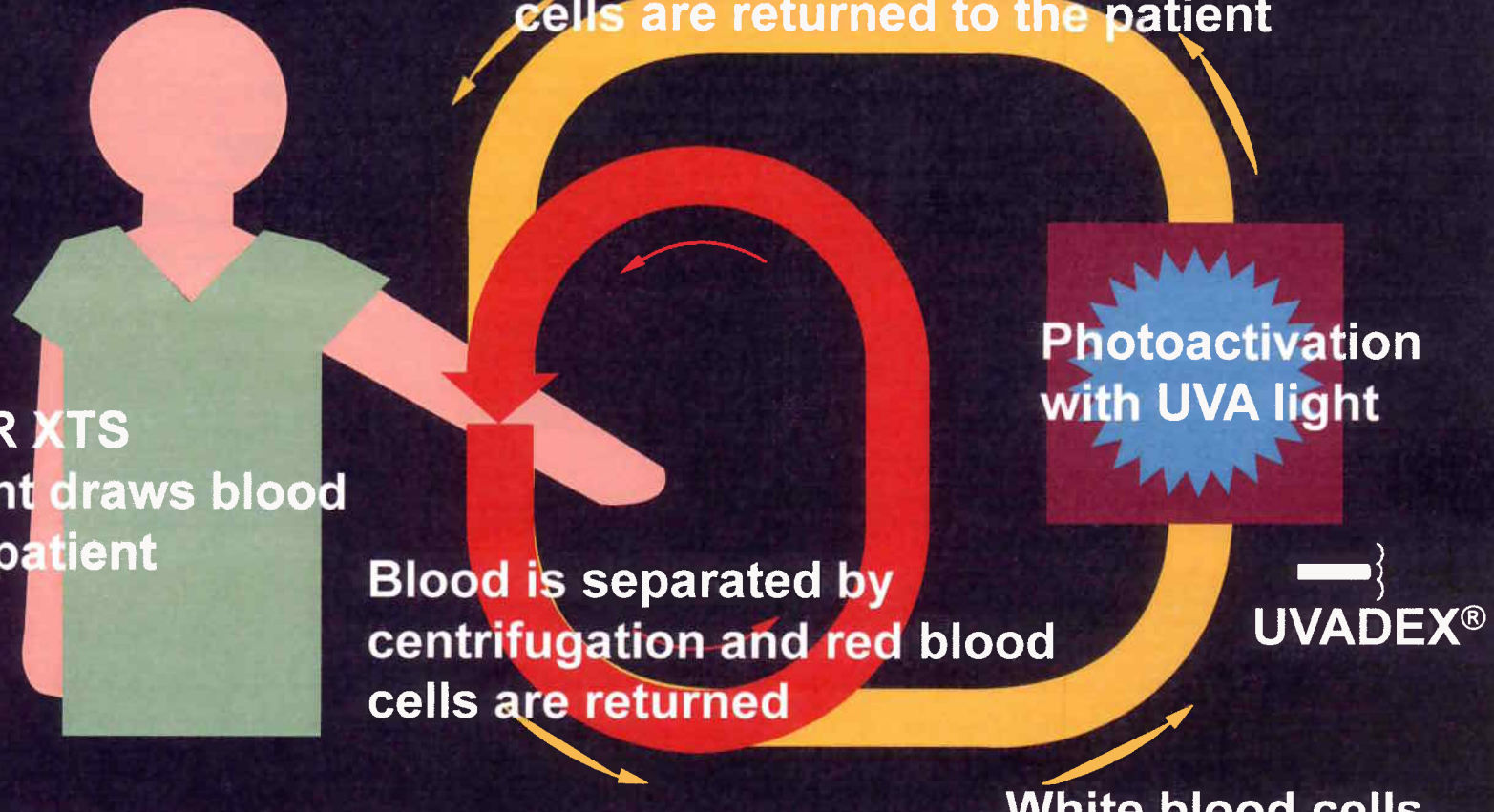

EXHIBIT B

New Therakos Photopheresis System

Therakos℠
Immune Cell Therapy

Utilize continuous flow technology to provide significantly

- ✓ **Shorter treatment times**
- ✓ **Smaller extracorporeal volumes**

The new technology will result in increased patient safety and convenience

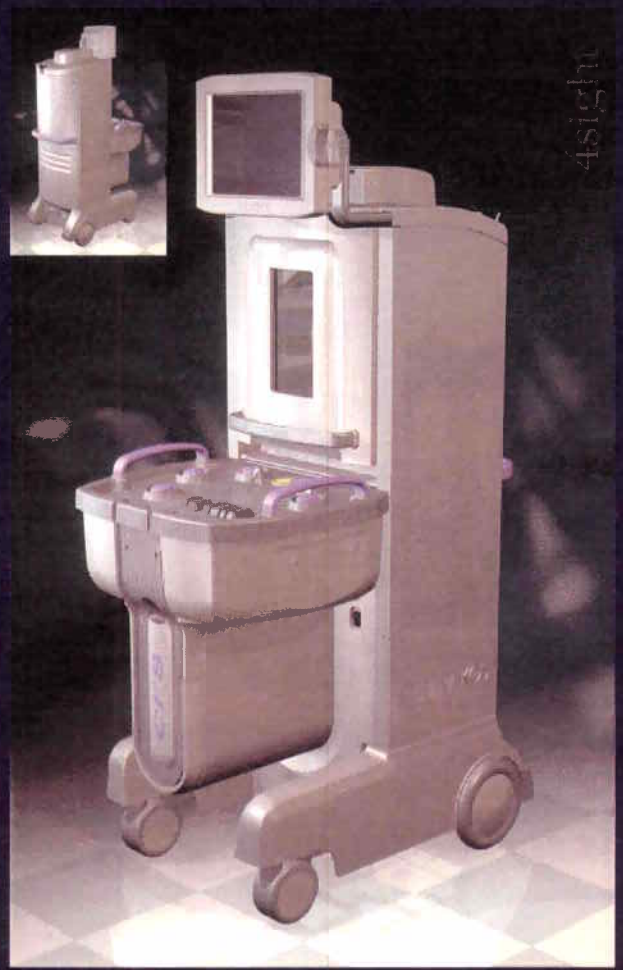

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EXHIBIT C

UVADEX
(methoxsalen)
Important Information

UVADEX®

Rx ONLY.

(Methoxsalen)

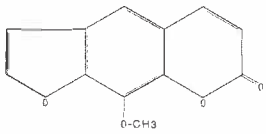
STERILE SOLUTION, 20 mcg/mL

Caution: Read the UVAR™ XTS™ or THERAKOS™ CELLEX™ Photopheresis System Operator's Manual prior to prescribing or dispensing this medication.

UVADEX® (methoxsalen) Sterile Solution should be used only by physicians who have special competence in the diagnosis and treatment of cutaneous T-cell lymphoma and who have special training and experience in the UVAR™ XTS™ or THERAKOS™ CELLEX™ Photopheresis System. Please consult the appropriate Operator's Manual before using this product.

DESCRIPTION

Methoxsalen is a naturally occurring photoactive substance found in the seeds of the Ammi majus (Umbelliferae) plant. It belongs to a group of compounds known as psoralens or furocoumarins. The chemical name of methoxsalen is 9-methoxy-7H-furo[3,2-g][1]-benzopyran-7-one; it has the following structure:



Each mL of UVADEX® (methoxsalen, 8-methoxypsoralen) Sterile Solution contains methoxsalen 20 mcg, propylene glycol 50 mg, sodium chloride 8 mg, sodium acetate 1.75 mg, ethanol 0.05 mL, glacial acetic acid 0.0012 mL, and Water for Injection q.s. to 1.0 mL.

UVADEX® is used in combination with the UVAR™ XTS™ Photopheresis System to extracorporeally treat leukocyte enriched buffy coat.

CLINICAL PHARMACOLOGY

Mechanism of action: The exact mechanism of action of methoxsalen is not known. The best-known biochemical reaction of methoxsalen is with DNA. Methoxsalen, upon photoactivation, conjugates and forms covalent bonds with DNA which leads to the formation of both monofunctional (addition to a single strand of DNA) and bifunctional adducts (crosslinking of psoralen to both strands of DNA). Reactions with proteins have also been described.

For the palliative treatment of Cutaneous T-Cell Lymphoma, Photopheresis consists of removing a portion of the patient's blood and separating the red blood cells from the white cell layer (buffy coat) by centrifugation. The red cells are returned to the patient and the UVADEX® Sterile Solution is then injected into the instrument and mixed with the buffy coat. The instrument then irradiates this drug-cell mixture with ultraviolet light (UVA light, 320-400 nm) and returns the treated cells to the patient. See the appropriate Operator's Manual for details of this process. Although extracorporeal phototherapy exposes less than 10% of the total body burden of malignant cells to methoxsalen plus light, some patients achieve a complete response. Animal studies suggest that the photopheresis may activate an immune-mediated response against the malignant T-cells.

Use of the UVAR™ and UVAR™ XTS™ Systems after oral administration of methoxsalen were previously approved for the treatment of Cutaneous T-Cell Lymphoma. Interpatient variability in peak plasma concentration after an oral dose of methoxsalen ranges from 6 to 15 fold. UVADEX® is injected directly into the separated buffy coat in the instrument in an attempt to diminish this interpatient variability and to improve the exposure of the cells to the drug.

Methoxsalen is reversibly bound to serum albumin and is also preferentially taken up by epidermal cells. Methoxsalen is rapidly metabolized in humans, with approximately 95% of the drug excreted as metabolites in the urine within 24 hours.

Systemic administration of methoxsalen followed by UVA exposure leads to cell injury. The most obvious manifestation of this injury after skin exposure is delayed erythema, which may not begin for several hours and peaks at 48-72 hours. The inflammation is followed over several days to weeks, by repair which is manifested by increased melanization of the epidermis and thickening of the stratum corneum.

The total dose of methoxsalen delivered in UVADEX® is substantially lower (approximately 200 times) than that used with oral administration.

CLINICAL STUDIES

Three single-arm studies were performed to evaluate the effectiveness of photopheresis in the treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL). In the first study (CTCL 1), 39 patients were treated with the oral formulation of methoxsalen in conjunction with the UVAR™ Photopheresis System. The second study (CTCL 2) was a 5-year post approval follow-up of 57 CTCL patients that was conducted to evaluate long-term safety. This study also used the oral dosage formulation of methoxsalen. In the third study (CTCL 3), 51 patients were treated with the UVADEX® formulation of methoxsalen in conjunction with the UVAR™ Photopheresis System. In study CTCL 3, 86% of the patients were Caucasian, the median age was 62 years, and the average number of prior therapies was 4.3.

In study CTCL 1, prednisone up to 10 mg/day was permitted in addition to topical steroids. In CTCL 2, there was no concomitant medication restriction. In CTCL 3, topical steroids were permitted only for the treatment of fissures on the soles of the feet and the palms of hands. All other steroids, topical or systemic, were prohibited.

In all three studies, patients were initially treated on two consecutive days every four to five weeks. If the patient did not respond after four cycles, treatment was accelerated to two consecutive days every other week. If the patient did not respond after four cycles at the accelerated schedule, the patient was treated on two consecutive days every week. If the patient still did not respond after four cycles of weekly treatments, the schedule was increased to three consecutive days every week for three cycles. In study CTCL 3, 15 of the 17 responses were seen within six months of treatment. Only two patients responded to treatment after six months. Clinical experience does not extend beyond this treatment frequency and there is no evidence to show that treatment with UVADEX® beyond six months or using a different schedule provided additional benefit.

Overall skin scores were used in the clinical studies of photopheresis to assess the patient's response to treatment. The patient's baseline skin score was used for comparison with subsequent scores. A 25% reduction in skin score maintained for four consecutive weeks was considered a successful response to photopheresis therapy. Table 1 indicates the percent of successful responses within six months of beginning therapy for all patients who received at least one course of photopheresis. Only patients with patch plaque, extensive plaque and erythrodermic disease were enrolled in these studies. No patients with disease in the tumor phase were treated. There are no data available regarding the efficacy of UVADEX® in patients with disease in the tumor phase.

Table 1: Percentage of Successful Responses
Within Six Months of Beginning Therapy

Study	Response % Within Six Months
CTCL 3 (UVADEX™)	17/51 (33)
CTCL 2 (oral methoxsalen)	16/57 (28)
CTCL 1 (oral methoxsalen)	21/39 (54)

Although the response rate with UVADEX® in CTCL 3 was similar to with oral methoxsalen in CTCL 2, the possibility that UVADEX® is inferior in efficacy to oral methoxsalen cannot be excluded due to the design and size of the clinical trials. The higher response rate with oral methoxsalen in CTCL 1 may be partly due to patients receiving more treatments (mean of 64 in CTCL 1, 31 in CTCL 2, and 20 in CTCL 3), and to the administration of systemic steroids in CTCL 1.

Retrospective analyses of three clinical benefit parameters from the Body Area Severity Scores in CTCL 3 suggested a correlation between skin score response and improvement in edema, scaling and resolution of fissures.

INDICATIONS AND USAGE

UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the UVAR™ XTS™ or THERAKOS™ CELLEX™ Photopheresis System in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

CONTRAINDICATIONS

PHOTOSENSITIVITY: UVADEX® (methoxsalen) Sterile Solution is contraindicated in patients exhibiting idiosyncratic reactions to psoralen compounds. Patients possessing a specific history of a light sensitive disease state should not initiate methoxsalen therapy. Diseases associated with photosensitivity include lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum and albinism.

UVADEX® Sterile Solution is contraindicated in patients with aphakia, because of the significantly increased risk of retinal damage due to the absence of lenses.

WARNINGS

Concomitant Therapy: Special care should be exercised in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents such as anthralin, coal tar or coal tar derivatives, griseofulvin, phenothiazines, nalidixic acid, halogenated salicylanilides (bacteriostatic soaps), sulfonamides, tetracyclines, thiazides, and certain organic staining dyes such as methylene blue, toluidine blue, rose bengal and methyl orange.

Carcinogenicity, Mutagenesis, Impairment of Fertility: Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. In a prospective study of 1380 patients given PUVA therapy for psoriasis, 237 patients developed 1422 cutaneous squamous cell cancers. This observed incidence of cutaneous carcinoma is 17.6 times that expected for the general population. Previous cutaneous exposure to tar and UVB treatment, ionizing radiation or arsenic increased the risk of developing skin carcinomas after PUVA therapy. Because the dose of methoxsalen with UVADEX® therapy is about 200 times less than with PUVA and the skin is not exposed to high cumulative doses of UVA light, the risk of developing skin cancer following UVADEX® therapy may be lower.

Methoxsalen was carcinogenic in male rats that were given the drug by oral gavage five days per week for 103 weeks at doses of 37.5 and 75 mg/kg. The 37.5 mg/kg dose is about 1900 times greater than a single human methoxsalen dose during extracorporeal photopheresis treatment on a body surface area basis. The neoplastic lesions in rats included adenomas and adenocarcinomas of the tubular epithelium of the kidneys, carcinoma or squamous cell carcinoma of the Zymbal gland and alveolar or bronchiolar adenomas. Topical or intraperitoneal methoxsalen is a potent photo-carcinogen in albino mice and hairless mice.

With S9 activation, methoxsalen is mutagenic in the Ames test. In the absence of S9 activation and UV light, methoxsalen is clastogenic in vitro (sister chromatid exchange and chromosome aberrations in Chinese hamster ovary cells). Methoxsalen also causes DNA damage, interstrand cross-links and errors in DNA repair.

Pregnancy: Methoxsalen may cause fetal harm when given to a pregnant woman. Doses of 80 to 160 mg/kg/day given during organogenesis caused significant fetal toxicity in rats. The lowest of these doses, 80 mg/kg/day, is over 4000 times greater than a single dose of UVADEX® on a mg/m^2 basis. Fetal toxicity was associated with significant maternal weight loss, anorexia and increased relative liver weight. Signs of fetal toxicity included increased fetal mortality, increased resorptions, late fetal death, fewer fetuses per litter, and decreased fetal weight. Methoxsalen caused an increase in skeletal malformation and variations at doses of 80 mg/ kg/day and above. There are no adequate and well-controlled studies of methoxsalen in pregnant women. If UVADEX® is used during pregnancy, or if the patient becomes pregnant while receiving UVADEX®, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

PRECAUTIONS

General: *ACTINIC DEGENERATION:*
After methoxsalen administration, exposure to sunlight and/or ultraviolet radiation may result in "premature aging" of the skin.

BASAL CELL CARCINOMAS:
Patients exhibiting multiple basal cell carcinomas or having a history of basal cell carcinomas should be diligently observed and treated.

SKIN BURNING:
Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of methoxsalen is exceeded or precautions not followed.

THE FORMATION OF CATARACTS:
Exposure to large doses of UVA light causes cataracts in animals. Oral methoxsalen exacerbates this toxicity. The concentration of methoxsalen in the human lens is proportional to the concentration in serum. Serum methoxsalen concentrations are substantially lower after extracorporeal UVADEX® treatment than after oral methoxsalen treatment. Nevertheless, if the lens is exposed to UVA light while methoxsalen is present, photoactivation of the drug may cause adducts to bind to biomolecules within the lens. If the lens is shielded from UVA light, the methoxsalen will diffuse out of the lens in about 24 hours.

Patients who use proper eye protection after PUVA therapy (oral methoxsalen) appear to have no increased risk of developing cataracts. The incidence of cataracts in these patients five years after their first treatment is about the same as that in the general population. Patients should be told emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after UVADEX® treatment. They should wear these glasses any time they are exposed to direct or indirect sunlight, whether they are outdoors or exposed through a window.

Information for Patients:
Patients should be told emphatically to wear UVA-absorbing, wrap-around sunglasses and cover exposed skin or use a sunblock (SP 15 or higher) for the twenty-four (24) hour period following treatment with methoxsalen, whether exposed to direct or indirect sunlight in the open or through a window glass.

Drug Interactions:
See **Warnings** Section.

Carcinogenesis, Mutagenesis, and Impairment of Fertility:
See **Warnings** Section.

Pregnancy:
Pregnancy Category D. See **Warnings** Section.

Nursing Mothers:
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methoxsalen is administered to a nursing woman.

Pediatric Use:
Safety in children has not been established. Potential hazards of long-term therapy include the possibilities of carcinogenicity and cataractogenicity as described in the Warnings Section as well as the probability of actinic degeneration which is also described in the Warnings Section.

ADVERSE REACTIONS

Side effects of photopheresis (UVADEX® used with the THERAKOS™ Photopheresis System) were primarily related to hypotension secondary to changes in extracorporeal volume (>1%). In study CTCL 3 (UVADEX®), six serious cardiovascular adverse experiences were reported in five patients (5/51, 10%). Five of these six events were not related to photopheresis and did not interfere with the scheduled photopheresis treatments. One patient (1/51, 2%) with ischemic heart disease had an arrhythmia after the first day of photopheresis that was resolved the next day. Six infections were also reported in five patients. Two of the six events were Hickman catheter infections in one patient, which did not interrupt the scheduled photopheresis. The other four infections were not related to photopheresis and did not interfere with scheduled treatments.

OVERDOSAGE

There are no known reports of overdosage with extracorporeal administration of methoxsalen. However, in the event of overdosage, the patient should be kept in a darkened room for at least 24 hours.

DRUG DOSAGE AND ADMINISTRATION

Each UVADEX® treatment involves collection of leukocytes, photoactivation, and reinfusion of photoactivated cells. UVADEX® (methoxsalen) Sterile Solution is supplied in 10 mL vials containing 200 mcg of methoxsalen (concentration of 20 mcg/mL). The UVAR™ XTS™ or THERAKOS™ CELLEX™ Photopheresis System Operator's Manual should be consulted before using this product.

During treatment with the UVAR™ XTS™ or THERAKOS™ CELLEX™ Photopheresis System, the dosage of UVADEX® for each treatment will be calculated according to the treatment volume.

- The prescribed amount of UVADEX® should be injected into the recirculation bag prior to the Photactivation Phase using the formula:

  TREATMENT VOLUME X 0.017 = mL of UVADEX® for each treatment
  Example: Treatment volume of 240 mL X 0.017 = 4.1 mL of UVADEX®

Frequency/Schedule of Treatment: Normal Treatment Schedule:
Treatment is given on two consecutive days every four weeks for a minimum of seven treatment cycles (six months).

Accelerated Treatment Schedule:
If the assessment of the patient during the fourth treatment cycle (approximately three months) reveals an increased skin score from the baseline score, the frequency of treatment may be increased to two consecutive treatments every two weeks. If a 25% improvement in the skin score is attained after four consecutive weeks, the regular treatment schedule may resume. Patients who are maintained in the accelerated treatment schedule may receive a maximum of 20 cycles. There is no clinical evidence to show that treatment with UVADEX® beyond six months or using a different schedule provides additional benefit. In study CTCL 3, 15 of the 17 responses were seen within six months of treatment and only two patients responded to treatment after six months.

HOW SUPPLIED

UVADEX® (methoxsalen) Sterile Solution 20 mcg/mL in 10 mL vials (NDC 64067-216-01), and cartons of 12 vials (NDC 64067-216-01). The drug product must be stored between 59°F (15°C) and 86°F (30°C).

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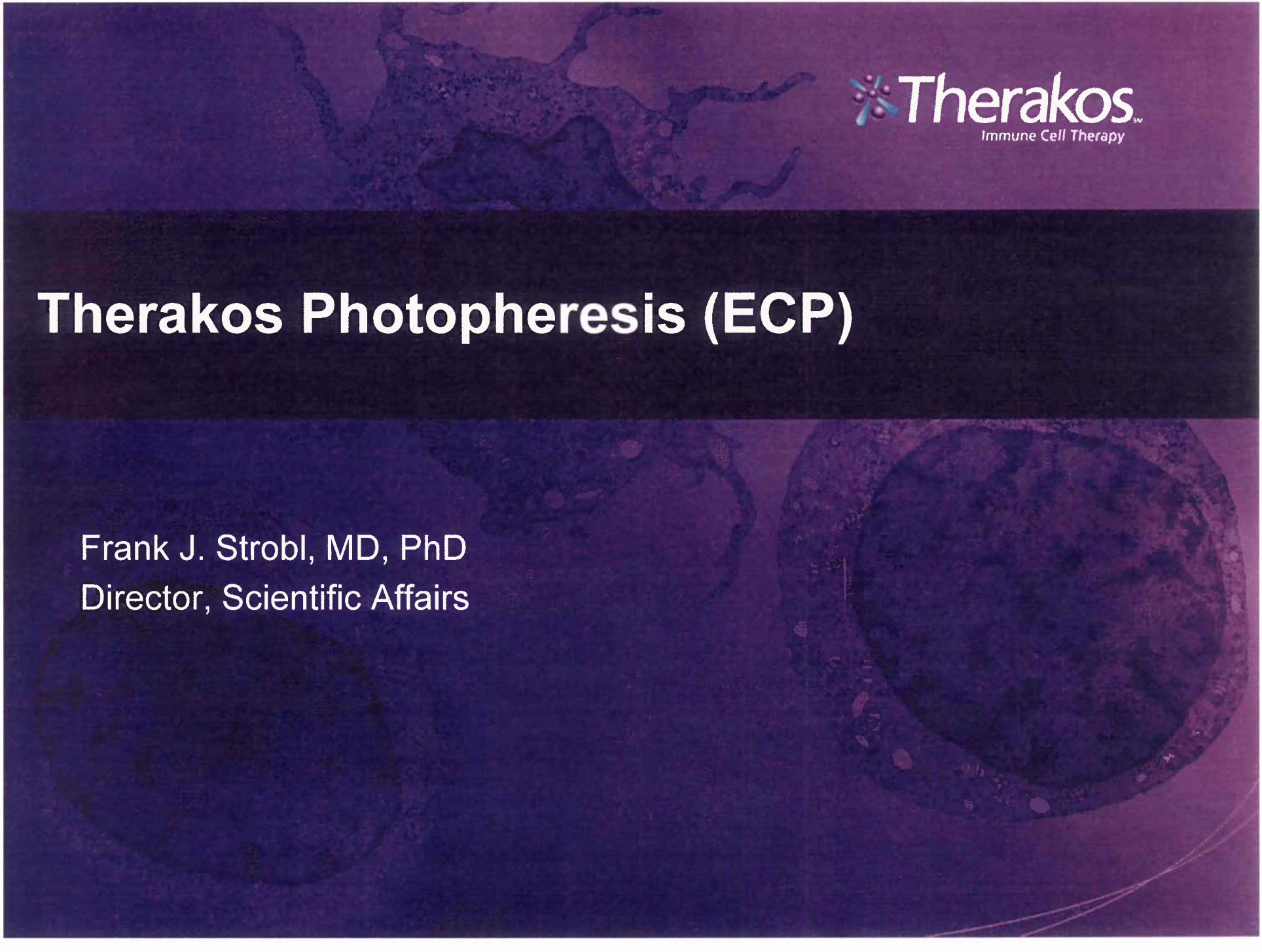
EXHIBIT D



Agenda

Therakos℠
Immune Cell Therapy

- History of Photopheresis
- THERAKOS Photopheresis
- Clinical Experience
- Clinical Trials

Therakos
Immune Cell Therapy

History of Therakos Photopheresis